CARELLA BYRNE CECCHI BRODY & AGNELLO, PC
James E. Cecchi
5 Becker Farm Road
Roseland, NJ 07068-1739
Telephone: (973) 994-1700

Liaison Counsel for the Proposed Class

LABATON SUCHAROW LLP
Christine M. Fox (*pro hac vice*)
Joseph Cotilletta
James M. Fee (*pro hac vice*)
140 Broadway
New York, NY 10005
Telephone: (212) 907-0700

KESSLER TOPAZ MELTZER & CHECK, LLP
Andrew L. Zivitz (*pro hac vice*)
Matthew L. Mustokoff (*pro vice hac pending)*
Jamie M. McCall *(pro vice hac pending)*
Margaret E. Mazzeo (*pro hac vice*)
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706

Co-Lead Counsel for Lead Plaintiffs SEB Investment Management AB and Public Employees' Retirement System of Mississippi, and the Proposed Class

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CITY OF WARWICK RETIREMENT SYSTEM, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

CATALENT, INC., JOHN CHIMINSKI, ALESSANDRO MASELLI, and THOMAS CASTELLANO,

Defendants.

Case No: 3:23-cv-01108-ZNQ

JURY TRIAL DEMANDED

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

TABLE OF CONTENTS

Page

Lead Plaintiffs SEB Investment Management AB and Public Employees' Retirement System of Mississippi (together, "Lead Plaintiffs"), individually and on behalf of all others similarly situated, by their undersigned counsel, hereby bring this Amended Class Action Complaint (the "Complaint") against Catalent, Inc. ("Catalent," or the "Company"), John Chiminski, Alessandro Maselli, and Thomas Castellano (collectively, "Defendants").[1] The allegations herein are based on Lead Plaintiffs' personal knowledge as to their own acts, and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of Co-Lead Counsel, which includes a review of: U.S. Securities and Exchange Commission ("SEC") filings by Catalent; securities analysts' reports and advisories about the Company; press releases and other public statements issued by the Company; media reports about the Company; interviews with former employees of Catalent, and others with knowledge of the matters alleged herein; and consultation with experts in the areas of loss causation and damages.[2] Co-Lead Counsel's investigation into the matters alleged herein is ongoing and many relevant facts are known only to, or are exclusively within the custody or control of, the Defendants. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein, after a reasonable opportunity for discovery. On behalf of themselves and the class they seek to represent, Lead Plaintiffs allege as follows:

---

[1] Defendants Chiminski, Maselli, and Castellano are referred to herein as the "Individual Defendants."

[2] Confidential witnesses ("CWs") will be identified herein by number (CW-1, CW-2). All CWs will be described in the masculine to protect their identities.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons or entities who or which, during the period from August 30, 2021 through May 7, 2023, inclusive (the "Class Period"), purchased or otherwise acquired publicly traded common stock or exchange-traded call options or sold exchange-traded put options of Catalent, and were damaged thereby. Lead Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

2. As an outsourced drug manufacturer for pharmaceutical and biotech companies, Catalent initially benefited from the COVID-19 pandemic (also referred to herein as "COVID-19," "COVID," or the "pandemic").[3] In early 2020, Catalent took on numerous large-scale COVID projects, including filling vaccines into syringes for Johnson & Johnson, Moderna, and AstraZeneca. Those projects catapulted the Company's quarterly revenues to record highs, which averaged approximately $940 million between April 2020 and March 2021, a 40% jump over pre-COVID revenues. Indeed, Catalent almost doubled its business during the first year of the pandemic when the bulk of vaccines were administered.[4] Catalent's success during the early stages of the pandemic caused its stock price to soar to record highs.

3. But by mid-2021, as the pandemic wore on, demand for vaccine products decreased significantly because vaccinations had already been administered to a large number of

[3] Catalent is a multinational corporation that manufactures and packages drugs into delivery devices fit for human consumption (*i.e.*, pre-filled syringes, vials, pills, etc.) pursuant to long-term supply contracts with pharmaceutical companies. Catalent directly sells these products to pharmaceutical companies which later sell them through the supply chain to healthcare providers (*i.e.*, hospitals, clinics, etc.), which administer them to patients, who are the end consumers.

[4] Prior to the onset of the pandemic, Catalent's quarterly revenue averaged approximately $669 million between April 2018 and March 2020. During the period that those revenues were reported to the market, Catalent stock had an average closing price of approximately $45.70 per share.

potential patients. When demand for the Company's vaccine-related work started to drop off, Defendants were in the unenviable position of having: (i) excess production capacity at Catalent's newly expanded production facilities; (ii) bloated headcount that had been rapidly increased for vaccine production in 2020 and early 2021; and (iii) increasing costs for remediation of quality control issues attributable, in part, to its rapid expansion.

4. In order to mask falling demand for Catalent's vaccine products and continue to report growing revenues across both of its operating segments during the Class Period, Defendants engaged in an accounting scheme to artificially inflate the Company's revenues and misled investors into believing that Catalent was generating sustainable revenue growth from non-vaccine products which Defendants explicitly represented would replace decreasing vaccine revenues. This multi-faceted scheme gave Catalent the appearance of continued growth, causing its stock price to reach new highs. Meanwhile, to keep pace with its lofty growth targets while its vaccine revenues were plummeting, Defendants were cutting corners on safety and quality control procedures at three of Catalent's most important manufacturing facilities and lying to the market about it.

5. In furtherance of their fraud, Defendants made false and misleading statements and omissions about key areas of Catalent's business. For ease of reference, the false statements have been categorized as follows: (i) the Quality Control Statements; (ii) the GAAP Compliance Statements;[5] and (iii) the Non-Vaccine Demand Statements.

6. The first category of false and misleading statements are the Quality Control Statements. Throughout the Class Period, Defendants made materially false and misleading statements and omissions about: (i) the Company's compliance with Current Good

[5] "GAAP" refers to Generally Accepted Accounting Principles.

Manufacturing Practices ("CGMP") which are quality control and safety regulations that are enforced by the FDA; and (ii) the ongoing operational challenges that plagued three of the Company's most important production facilities including the significant disruption occasioned by efforts to remediate issues identified by the FDA at those facilities.

7. However, the Quality Control Statements were materially false and misleading when made in that they failed to disclose the following adverse facts, which were known to or recklessly disregarded by Defendants: (i) Catalent disregarded regulatory rules, industry standards, and internal Standard Operating Procedures ("SOPs") at key production facilities located in Bloomington, Indiana, Brussels, Belgium, and Harmans, Maryland (near the Baltimore-Washington International Airport ("BWI"))[6] in order to rapidly produce product that was used to pad the Company's financial results through improper revenue recognition in violation of U.S. GAAP; and (ii) Defendants' disregard of quality assurance at Catalent's key production facilities caused the Company serious regulatory problems including three Form 483 inspection reports from the FDA during the Class Period for serious infractions,[7] partial and complete facility shutdowns, increased costs, customer cancellations, decreases in customer spending, and reputational harm to Catalent.

8. Former Catalent employees and contractors confirm, among other things: (i) severe quality control and quality assurance issues at the Bloomington, Brussels, and Harmans/BWI facilities that resulted in repeated regulatory FDA violations, huge backlogs of

[6] The Catalent facility in Harmans, Maryland near the BWI airport is referred to herein as Harmans or Harmans/BWI.

[7] The FDA issues a Form 483 to company management at the conclusion of an inspection when the FDA has observed any conditions that may constitute statutory violations under the FDA's purview, including CGMP violations. Such violations include conditions or practices indicating that any drug or device has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

unresolved SOP deviations and management overriding procedures designed to correct those SOP deviations; (ii) routinely contaminated and unsterile conditions at facilities manufacturing pharmaceuticals for customers including, but certainly not limited to, lettuce, oil and vinegar, and blood in "the fill" portion of the manufacturing process for vaccines produced at the Bloomington facility; (iii) a constant push by Catalent's senior management to keep manufacturing product despite "major quality issues" in order "to meet revenue deadlines;" (iv) consistent complaints by large customers including Sarepta and AveXis for Catalent to stop producing their products so quickly and instead focus on improving the quality of the products; (v) tens of millions of dollars' worth of product not released at one facility due to a serious backlog in correcting SOP deviations; (vi) hundreds of millions of dollars' worth of batches that could not be released at another facility due to missing documentation, batch contamination, and quality issues; (vii) disputes with customers and the exodus of customers because of issues around billing for ruined batches discarded due to quality issues; and (viii) customers leaving Catalent because of the sterility issues identified by the FDA in its Form 483 issued to the Bloomington facility in September 2022.

9. The second category of false and misleading statements are the GAAP Compliance Statements. Throughout the Class Period, Defendants made materially false and misleading statements and omissions about: (i) the Company's compliance with GAAP in Catalent's revenue recognition practices; (ii) the appropriateness, under GAAP, of the level of the Company's inventory reserves for excess, unsaleable, and expiring inventory related to the manufacture of COVID vaccines and other biologics and drug products; and (iii) Catalent's internal controls over financial reporting related to revenue recognition and forecasting.

10. The GAAP Compliance Statements were materially false and misleading when made in that they failed to disclose the following adverse facts, which were known to or recklessly disregarded by Defendants: (i) Catalent materially overstated its revenue and earnings by improperly recognizing revenue in violation of GAAP; (ii) Catalent had a material weakness in its internal control over financial reporting related to revenue recognition, including admittedly poor internal controls relating to the accounting for contract modifications, including price concessions offered to customers; and (iii) Catalent materially understated its inventory reserves for excess, unsaleable, and expiring inventory throughout the Class Period in violation of GAAP, by failing to timely account for significant increases in inventory levels during the Class Period and substantial changes in customer demand and increasing customer disputes and unrecorded bad debt levels for raw materials, component inventory, and work in progress. As a result of the foregoing, Defendants lacked a reasonable basis for their statements about Catalent's financial performance during the Class Period.

11. Indeed, former Catalent employees and contractors confirm repeated GAAP violations by Catalent, including: (i) journal entries being made without sufficient supporting documentation, without compliance with the Sarbanes-Oxley Act of 2002 ("SOX"), and without requisite approval; (ii) invoices or sales orders issued which violated customer contracts on how and when to bill those customers; (iii) revenue recognized in violation of ASC 606 which is the governing regulation on recognizing revenue on sales contracts; (iv) senior finance executives directing staff accountants to make fictitious and unsupported journal entries to make Catalent's financial results appear stronger than they actually were; and (v) the understatement of bad debt for uncollectible invoices.

12. Former Catalent employees also confirm: (i) pressure applied by the Individual Defendants on Catalent employees to do everything they could to recognize revenue; (ii) monthly meetings between the Project Management ("PM") team and Catalent finance where the PMs were instructed to "find the revenue wherever you can;" (iii) that Catalent was producing product way faster than its customers wanted and frequently against the clients' explicit wishes in order to accelerate revenue recognition on deals with its biggest clients. Indeed, the Company's quality teams were unable to keep up with the amount and speed of product being produced and its freezers were getting backed up, but Catalent needed the cash coming in; (iv) that the Company was acting as a distribution center for customers by holding their product for excessively long periods after production which struck employees as odd since most products had a shelf-life but were still sitting in freezers at Catalent for months which one witness characterized as "shady."

13. Former Catalent employees and contractors also confirm serious internal control issues at Catalent throughout the Class Period, including with the Company's inventory tracking methodology and inventory documentation (or lack thereof), and a failure to timely write off significant amounts of inventory that was unused, expired, unsaleable, or even unaccounted for. This resulted in Catalent billing large customers, including Sarepta, for materials those customers did not order or need. Indeed, multiple CWs confirm that a majority of the customers at Catalent's Harmans, Maryland facility were disputing their raw material invoices. Because of these disputes, customer payments were often delayed and/or needed to be partially written off or reversed through the issuance of a steady stream of credit memos. According to one former employee, "standard accounting did not occur at Catalent," adding that the Company was not reserving against old and uncollectible invoices. In approximately September 2022, Catalent's

Audit Committee, then-CFO Tom Castellano, and others in the corporate suite were presented with the "brutal findings" of an internal audit conducted at Harmans which noted serious control issues requiring remediation.

14. The third category of false and misleading statements are the Non-Vaccine Demand Statements. Starting in early 2022, Defendants made materially false and misleading statements and omissions about: (i) demand for the Company's gene therapy and other non-vaccine products in the Biologics and Pharma and Consumer Health segments (defined below) which the Company represented would offset declining vaccine revenues during the Class Period; and (ii) how quickly and easily Catalent would be able to transition its production lines and personnel from vaccine production to the production of other products at its key facilities including the Bloomington and Brussels facilities.

15. However, the Non-Vaccine Demand Statements also were materially false and misleading when made in that they failed to disclose the following adverse facts, which were known to or recklessly disregarded by Defendants: Catalent was experiencing lower levels of utilization across the Company's Biologics segment, a significant slowdown in customer spending, and broad-based delays in decision making from its large and small European and U.S.-based customers in both its Biologics and Pharma and Consumer Health segments.

16. Former Catalent employees confirm that it was "very evident" and "everyone knew" that there was going to be a "lull" after COVID and there was the "longstanding idea that we'd [Catalent] have to brace for that [the slowdown in demand for COVID vaccines]." Indeed, by no later than calendar Q2 2022, significant production capacity was opening up at the Bloomington facility as at least one vaccine customer was leaving Catalent and Catalent could not easily replace the business. Because of the lack of new non-vaccine business in the pipeline,

there was a "massive exodus" of Catalent Project Managers in the Fall 2022 because the PMs realized that there was no money coming in with the COVID vaccine business slowing down a lot and with "no [other] business in the pipeline."

17. Catalent's misrepresentations and omissions were revealed to the market through a series of disclosures starting on September 20, 2022, when the *Washington Post* released an article, after the close of trading, entitled, "FDA releasing millions of Moderna boosters as states warn of shortages." According to the article, the FDA had delayed the release of millions of COVID-19 vaccine booster shots filled by Catalent because of the poor inspection and resulting Form 483 issued to Catalent at its Bloomington facility. FDA officials raised concerns that vaccines packaged at the Bloomington facility could be contaminated because the facility was not sufficiently sterile. On this news, Catalent's stock price ***declined by 9.3 percent*** over two trading sessions, falling from $87.15 per share on September 20, 2022 to close at $79.06 per share on September 22, 2022.

18. On November 1, 2022, in connection with Catalent's release of disappointing first quarter (Q1) 2023 financial results, for the quarter ended September 30, 2022, Catalent disclosed that its quarterly earnings had declined to zero, and lowered its fiscal year 2023 revenue guidance by approximately $350 million, due to, among other things, lower spend by some of its pharma and consumer health customers. The earnings miss and revised guidance revealed that demand for Catalent products in the Pharma and Consumer Health segment was much weaker than the Company had been touting. On this news, Catalent's stock price ***plunged by 31.7 percent*** over two trading sessions, to close at $44.90 per share on November 2, 2022. Despite these disclosures, Defendants continued to issue false and misleading statements related to the

Company's compliance with GAAP, demand for its products, and quality control at its key facilities.

19. On November 16, 2022, Catalent revealed that it was carrying approximately $400 million in excess inventory, further revealing that the Company had misrepresented demand for its products as well as its purported ability to reasonably forecast demand. On this news, Catalent's stock price ***declined by 14 percent***, over two trading sessions, to close at $42.07 per share on November 17, 2022. Despite these disclosures, Defendants failed to adequately reserve for unsaleable and excess inventory; and instead continued to issue false and misleading statements related to the Company's compliance with GAAP, demand for its products, and quality control at its key facilities.

20. On December 8, 2022, GlassHouse Research published a report claiming that Catalent had been prematurely recognizing revenues of at least $568.2 million in violation of GAAP. The report detailed numerous red flags that were indicative of Catalent's improper accounting practices. These red flags included: (i) the rapid increase in Catalent's contract asset and inventory balances; (ii) declining customer deposits; (iii) executive turnover; and (iv) scrutiny of the Company's revenue accounting by regulators. The report also described how Catalent's direct customers were stuffed with excess inventory which "will take years to unwind." On the news of the GlassHouse Research report, Catalent's stock price ***declined 3.6 percent*** to close at $45.54 per share on December 8, 2022.

21. On April 14, 2023, Catalent revealed that it expected productivity issues and higher-than-expected costs at three of its key manufacturing facilities (the Bloomington, Brussels, and Harmans/BWI facilities) to materially and adversely impact the Company's financial results for Q3 2023 (ended March 31, 2023), and its outlook for the remainder of fiscal

2023 (ended June 30, 2023). The Company explained that it was unable to achieve anticipated productivity levels and associated revenue due to costs related to remediation at the Bloomington and Harmans/BWI facilities following regulatory inspections that resulted in Form 483s and other "operational challenges" the Company was facing. On this news, Catalent's stock price ***declined 26.8 percent*** to close at $46.32 per share on April 14, 2023. Despite these disclosures, Defendants continued to issue false and misleading statements related to the Company's compliance with GAAP, demand for its products, and quality control at its key facilities.

22. Then, on May 8, 2023, Catalent shocked the market by disclosing that it would be delaying the release of its third fiscal quarter results and would be filing a Form 12b-25, Notification of Late Filing, with the SEC because, in addition to the productivity and cost issues identified on April 14, 2023, the Company also: (i) identified accounting issues related to revenue recognition at the Bloomington facility; (ii) expected to record a goodwill write-down in its consumer health segment; and (iii) significantly reduced its forecasts for fiscal 2023 (ended June 30, 2023). On this news, Catalent's stock price ***declined 25.7 percent*** to close at $35.46 per share on May 8, 2023.

23. On May 19, 2023, after the end of the Class Period, Catalent held a Status Update call to further discuss the issues previously identified by the Company on April 14 and May 8, 2023. During the Status Update Call, Catalent announced that it expected to: (i) restate its financials for fiscal 2022, ended June 30, 2022, because of the improper recognition of $26 million in Q4 2022 in violation of GAAP; (ii) increase its inventory reserves by approximately $55 million related to unsaleable and expiring inventory of manufacturing components and raw materials at the Bloomington manufacturing facility; (iii) report a goodwill impairment of more than $200 million in the Company's consumer health segment; and (iv) assess the effectiveness

of the Company's internal controls over financial reporting and disclosure control and procedures.

24. On May 19, 2023, the Company also announced a significantly reduced revenue forecast for fiscal 2023 ended June 30, 2023 (with revenue down by approximately $450 million and EBITDA down by about $510 million at the midpoint) due to: (i) an admittedly botched forecasting system; (ii) price concessions given to certain customers; (iii) lost productivity and lost or seriously delayed revenues that "dropped through to the bottom line[;]" (iv) higher costs caused by the corrective remediation and other "operational challenges" at the Bloomington, Brussels, and Harmans/BWI manufacturing facilities; and (v) "pronounced declines in some existing commercial line value pharmaceutical products[,] delayed launches of some promising new prescription products[,] and lower consumer demand" in the Pharma and Consumer Health ("PCH") segment.

25. On June 12, 2023, Catalent finally filed its late Form 10-Q report for Q3 2023 (ended March 31, 2023) and its restated financial statements for fiscal 2022 ended June 30, 2022 because of the previously announced $26 million improper recognition of revenue. For Q4 2022, that revenue reversal reduced Adjusted EBITDA by 7%, and Adjusted Net Income and Adjusted Net Income per Share by 12% each. Notably, the improperly recognized revenue was material to Catalent's financial statements for Q4 2022, as ***Catalent's restated financials show that, but for the improper revenue recognition of $26 million, Catalent would have missed even the low end of Wall Street earnings guidance provided for Q4 2022***. Catalent also reported a material weakness in internal controls over financial reporting as of June 30, 2022 and recorded a $55 million charge in Q3 2023 to increase the Company's inventory reserves to account for unsaleable inventory.

26. On August 30, 2023, Catalent revealed that the filing of its Form 10-K for fiscal year 2023 (ended June 30, 2023) would be delayed as the Company "requires additional time to complete its procedures related to management's assessment of the effectiveness of its internal controls over financial reporting as of June 30, 2023 and other closing procedures." Then, on September 15, 2023, Catalent announced it had received notice from the NYSE that it was "not in compliance with the NYSE's continued listing requirements" as the Company had failed to file the 10-K by the extension date of September 13, 2023. This likely means that Catalent's material weakness in internal controls over financial reporting, which Catalent belatedly reported for the fiscal year ended June 30, 2022, still may be plaguing the Company.

27. All told, over the course of the Class Period, Catalent stock fell from a high above $141.00 to close at $35.46 per share on May 8, 2023, ***a 75% decline***. As a result of Defendants' fraud, Catalent stock dropped to pre-COVID levels, causing substantial losses to its investors as they learned the full extent of Catalent's quality control and internal control issues, and that Defendants' Class Period representations were riddled with materially misleading statements and omissions.

28. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Catalent securities, Lead Plaintiffs and other Class members have suffered significant damages. This action seeks to recover those damages.

II. JURISDICTION AND VENUE

29. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

30. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

31. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78 aa) as the alleged misstatements and the subsequent damages took place in this judicial district and Catalent is headquartered in this Judicial District.

32. In connection with the acts, conduct, and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

33. Court-appointed Lead Plaintiff Public Employees' Retirement System of Mississippi ("MissPERS") provides retirement benefits for individuals working in Mississippi government, public schools, universities, community colleges, municipalities, counties, the Legislature, highway patrol, and other such public entities. MissPERS is a sophisticated institutional investor that had more than $33.5 billion in total pension assets under management as of June 1, 2023. As set forth in the Certification previously submitted to the Court (ECF No. 12-3), Lead Plaintiff MissPERS purchased or otherwise acquired Catalent common stock at artificially inflated or artificially maintained prices during the Class Period and suffered damages thereby.

34. Court-appointed Lead Plaintiff SEB Investment Management AB ("SEB") is a leading asset management company in the Nordic region offering a full range of products for both private and institutional investors. SEB is a sophisticated institutional investor with billions of dollars in assets under management. As set forth in the Certification previously submitted to the Court (ECF No. 12-3), Lead Plaintiff SEB purchased or otherwise acquired Catalent common stock at artificially inflated or artificially maintained prices during the Class Period and suffered damages thereby.

35. Defendant Catalent provides development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, vaccines, and consumer health products at its over fifty facilities around the globe. Catalent is incorporated in Delaware and its principal executive office is located at 14 Schoolhouse Road, Somerset, New Jersey, 08873. Catalent's common stock trades on the New York Stock Exchange ("NYSE") under the ticker symbol "CTLT."

36. Defendant John Chiminski ("Chiminski") is the current Executive Chair of the Board of Directors of Catalent and previously served as the Company's Chief Executive Officer ("CEO") from the beginning of the Class Period through July 1, 2022. During his tenure as CEO, Chiminski signed Catalent's annual reports and SOX certifications stating that the financial information contained in the Company's financial reports was accurate and disclosed any material changes to Catalent's internal controls over financial reporting. Throughout his tenure as CEO, Chiminski also participated in the Company's quarterly earnings conference calls described herein.

37. Defendant Alessandro Maselli ("Maselli") serves as the Company's current CEO and President effective July 1, 2022 and, prior to that, served as the Company's President and Chief Operating Officer ("COO") since February 2019. During his tenure as CEO (July 1, 2022 through the end of the Class Period), Maselli signed Catalent's annual report and SOX certification stating that the financial information contained in the Company's financial reports was accurate and disclosed any material changes to Catalent's internal controls over financial reporting. Throughout his tenure as CEO, Maselli also participated in the Company's quarterly earnings conference calls described herein.

38. Defendant Thomas Castellano ("Castellano") served as the Company's Chief Financial Officer ("CFO") and Senior Vice President from June 1, 2021 through April 2023

when he left the Company. Castellano previously served as Catalent's Global Vice President of Operational Finance, from January 2020 to May 2021, and prior to that he served as the Company's Investor Relations Officer, Vice President Finance and Treasurer. During his tenure as CFO, Castellano signed Catalent's annual reports and SOX certifications stating that the financial information contained in the Company's financial reports was accurate and disclosed any material changes to Catalent's internal controls over financial reporting. Throughout his tenure as CFO, Castellano also participated in the Company's quarterly earnings conference calls described herein.

39. The Individual Defendants possessed the power and authority to control the contents of Catalent's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Catalent's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Catalent, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

40. The Company and the Individual Defendants are sometimes collectively, in whole or in part, referred to herein as the "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Company Overview: Biologics and PCH Segments

41. Catalent is a contract development and manufacturing organization ("CDMO") which provides drug development and manufacturing solutions at its more than fifty facilities

across the globe. Many of the services Catalent provides involve delivery technologies for various drugs, such as pre-filled syringes and vials. Catalent partners with consumer health, biopharma and cell and gene therapy customers to develop and manufacture consumer health products, small molecule drugs, biotherapeutics, cell and gene therapies, and products incorporating other novel modalities.

42. The Company's capabilities span across the drug development cycle, from preclinical through commercial manufacturing across a wide range of modalities and therapeutic categories. Catalent boasts that it operates more than "50 sites across the globe, manufacturing over 7,000 products across 1,000 different customers." Catalent boasts that it partners with nearly all of the top pharmaceutical companies, biotechs, generics companies, and consumer health companies.

43. Catalent conducts its business through two segments: (1) Biologics; and (2) Pharma and Consumer Health ("PCH"), which each generate about half of Catalent's total revenue.[8]

(a) The Biologics segment provides development and manufacturing for Catalent's drug products, drug substances, and cell and gene therapy offerings (with a significant portion of its business in drug products). Before the pandemic, the Biologics segment accounted for just 25% of Catalent's net revenue. The Biologics segment was Catalent's largest and

[8] Effective July 1, 2022, in connection with the appointment of Defendant Maselli as the Company's President and CEO, the Company changed its operating structure and reorganized its executive leadership team. This new organizational structure included a shift from four operating and reporting segments to two segments: (i) Biologics (which remained unchanged); and (ii) Pharma and Consumer Health, each of which represented approximately half of the Company's net revenue in fiscal 2022.

fastest-growing segment and was expected to be the primary driver of margin expansion for the Company. By February 2022, the Biologics segment accounted for 50% of Catalent's net revenue.

(b) The PCH segment mass produces commercially approved pills and gummies and includes the product offerings of the Company's three prior segments: (i) Softgel and Oral Technologies; (ii) Oral and Specialty Delivery; and (iii) Clinical Supply Services. PCH also encompasses the formulation, development, and manufacturing platforms for oral, nasal, inhaled, and topical dose forms, and clinical trial development and supply services. According to Defendant Maselli, the PCH segment "tends to have less variability on a quarter-to-quarter performance basis" and is also "a good source of cash flow for the organization."

44. Patients are the end consumers of medical products for which Catalent provides manufacturing and development services. However, Catalent's direct customers, or "channel partners" are typically pharmaceutical companies. Catalent provides manufacturing services for these channel partners, such as filling syringes with the channel partners' vaccines, which get packaged and shipped to the channel partners. The channel partners ultimately distribute these products to healthcare providers.

45. Some of Catalent's key channel partners include AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Moderna, and Pfizer. Catalent has long-term agreements with these channel partners to continuously supply them with inventory. These close relationships give the Company strong visibility into the needs of its channel partners,

particularly what level of inventory the channel partners will need to serve the demand of end consumers.

46. These long-term agreements with channel partners also dictate, in part, the benchmarks that Catalent must meet in order to recognize revenue. Under GAAP, Catalent is required to recognize revenue on its long-term agreements with its channel partners once the Company meets certain objective milestones (*i.e.*, products successfully passing quality inspection). Because Catalent recognizes a significant portion of this revenue *prior to* billing its customers, which reduces third-party transparency, these contracts are highly susceptible to accounting fraud through premature revenue recognition.

47. Between April 2018 and March 2020, prior to any COVID-related projects, Catalent's quarterly revenue averaged $669 million. During the period that these revenues were reported to the market, Catalent stock had an average closing price of $45.70 per share.

B. Catalent's Manufacturing Facilities: Biologics Segment

48. Catalent's largest two production facilities within the Biologics segment include a plant in Bloomington, Indiana which provides drug product filling and finishing services (the "Bloomington facility") and a gene therapy manufacturing site located in Harmans, Maryland near the BWI airport (called the "Harmans/BWI" or "Harmans" facility by Catalent). Catalent also has a smaller, but important, syringe filling facility in Brussels, Belgium (the "Brussels facility"). In addition, the Company has Biologics manufacturing facilities in: (i) Anagni, Italy; (ii) Limoges, France; and (iii) Madison, Wisconsin.

1. Bloomington Manufacturing Facility

49. The Bloomington, Indiana facility, a 950,000-square-foot facility, offers fill and finish services and commercial scale production. During the Class Period, the manufacturing facility in Bloomington played a "critical role" in Catalent's global vaccine production efforts. In

fiscal 2021 ended June 30, 2021, during the height of the pandemic, Catalent brought online two new vial-filling lines dedicated to the manufacture of products for two of the Company's COVID-19 vaccine customers (Moderna and Johnson & Johnson). In addition, a highspeed syringe filling-line at the site was added in fiscal 2022.

50. The Bloomington facility has been in Catalent's portfolio since October 2017 when Catalent completed the acquisition of Cook Pharmica LLC.

2. Harmans/BWI Facility

51. The Catalent Gene Therapy campus in Harmans, Maryland is located five miles from the BWI airport. At approximately 345,000 square feet, the Harmans/BWI facility houses two manufacturing facilities and 18 CGMP manufacturing suites, fill/finish, central services, testing labs, and a cold storage warehouse. The Harmans/BWI facility purportedly supports Phase 3 through commercial manufacturing of advanced therapeutic products including UpTempo Virtuoso adeno-associated virus (AAV) platform, and other viral vector-based therapies and vaccines. The main customers of the Harmans/BWI facility included AstraZeneca, Sarepta Therapeutics, and AveXis. The Harmans/BWI facility was acquired by Catalent in connection with its acquisition of gene therapy leader Paragon Bioservices, Inc. in May 2019.

3. Brussels Facility

52. The 265,000 square-foot site in Brussels, Belgium, described as Catalent's flagship European syringe filling facility, produces over 175 million units annually for the CDMO's customers, including Novo Nordisk for which Catalent fills Novo's weight loss drug Wegovy (semaglutide) injectible pens and its GlucaGen treatment for people with diabetes who experience low blood pressure. Catalent's Brussels facility also filled products for AMAG Pharmaceuticals' Vyleesi, Genentech's Pegasys, Guerbet's DOTAREM, and Seqirus Vaccines' Fluvirin.

C. COVID Projects Drive Massive Revenue Growth at Catalent

53. Much of Catalent's rapid growth since 2020, particularly in its Biologics segment, is attributable to its sale of vaccine-related products. In early 2020, Catalent took on numerous large-scale COVID vaccine projects, including filling vaccines into syringes for Johnson & Johnson, Moderna, and AstraZeneca. As Catalent was taking on these projects, it was expanding its facilities to meet the accelerating demand for vaccine-related drugs. Meanwhile, Defendants provided the market with very strong revenue guidance while touting the Company's ability to gauge customer demand.

54. The vaccine-related projects propelled the Company's quarterly revenues to record highs, which averaged $939 million between April 2020 and March 2021, a ***40 percent jump*** over pre-COVID revenues. Indeed, Catalent almost doubled its business during the first year of the pandemic when the bulk of vaccines were administered.[9] Catalent's success during the early stages of the pandemic caused its stock price to soar to record highs.

D. Catalent's Vaccine Revenue Growth Slows in Mid-2021

55. By mid-2021, as the pandemic wore on, demand for Catalent's vaccine products decreased significantly because vaccinations had already been administered to a large number of potential patients.

56. For example, Centers for Disease Control and Prevention ("CDC") data indicates that COVID vaccinations in the United States reached an all-time high of 4.5 million doses on

[9] Prior to the onset of the pandemic, Catalent's quarterly revenue averaged approximately $669 million between April 2018 and March 2020. During the period that those revenues were reported to the market, Catalent stock had an average closing price of approximately $45.70 per share.

April 1, 2021,[10] and averaged 1.5 million daily doses between December 14, 2020 and August 28, 2021. By comparison, CDC data indicates that average daily vaccination rate in the United States was under 484,000 during the Class Period.

E. The FDA Identifies Major Issues at Catalent Production Facilities

57. All of the Company's manufacturing facilities, including its Bloomington facility, the Brussels facility, and the Harmans/BWI facility, are required to abide by CGMP, quality control and safety regulations that are enforced by the FDA, which periodically inspects the Company's facilities and protocols.

58. The rapid expansion of production activity by Catalent leading up to the Class Period, specifically related to COVID vaccine production in late 2020 and early 2021, led to serious operational challenges at critical manufacturing facilities during the Class Period.

59. Catalent took on a huge influx of new employees during this ramp-up time and simultaneously promoted existing workers in order to keep up with demand. Thus, as described in further detail herein, many workers lacked sufficient training in their roles causing, among other things, serious and repeated deviations from Catalent's SOPs and observable conditions in violation of FDA regulations.

60. Due to the pandemic, in-person FDA inspections of manufacturing facilities like Catalent's Bloomington, Brussels, and Harmans/BWI sites were limited from April 3, 2020 until mid-2022. FDA "inspections" were, in large part, conducted remotely during this time and

[10] All vaccination date cites Edouard Mathieu et al., *A global database of COVID-19 vaccinations*, 5 NAT HUM BEHAV (2021). https://www.nature.com/articles/s41562-021-01122-8.

included the review of facility documentation.[11] Thus, during this time, Catalent's SOP deviations and CGMP violations went largely unchecked.

61. Once in-person FDA inspections resumed, Catalent could no longer hide its surfeit of regulatory violations. Indeed, during the Class Period, Catalent received at least three Form 483s from the FDA. The FDA issues a Form 483 to company management at the conclusion of an inspection when the FDA has observed any conditions that may constitute statutory violations under the FDA's purview, including CGMP violations. Such violations include conditions or practices indicating that a drug or device has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

1. Catalent's Brussels Facility Receives Multiple Form 483s During the Class Period

62. According to Jefferies' analyst David Windley, Catalent's Brussels facility "has been no stranger to 483s. Over the past decade, that site has been issued twelve Form 483s across the nine FDA inspection visits."[12] During the Class Period, the Brussels facility received two additional Form 483s—both observing issues related to sterility at the facility.

---

[11] According to the FDA website: "During this worldwide public health emergency, the FDA has used a variety of tools to oversee facilities that manufacture FDA-regulated products. These tools include record requests in advance of or in lieu of a drug facility inspection, relying on information from trusted regulatory partners, and remote interactive evaluations (such as remote livestreaming video of operations, teleconferences and screen sharing). We have used some or all of these approaches to evaluate facilities for human and animal medical products during the public health emergency when inspections of drug facilities were not possible due to travel or quarantine restrictions."

[12] Dan Stanton, *Catalent hit with FDA 483 at Belgian fill and finish facility,* BIOPROCESS INTERNATIONAL, (Jan. 7, 2002), https://bioprocessintl.com/bioprocess-insider/regulations/catalent-hit-with-fda-483-at-belgian-fill-and-finish-facility/.

(a) Brussels Facility: October 2021 Form 483

63. The FDA conducted an inspection from October 18, 2021 to October 26, 2021 at the Brussels facility. On October 26, 2021, the FDA issued a Form 483 pursuant to this inspection, stating it had found, among other things, several infractions including faulty air filtration systems, alarming bacterial growth, and subpar equipment maintenance.[13] In the Form 483, the FDA highlighted CGMP issues with Novo Nordisk's Wegovy production by Catalent.

64. The Form 483 cited seven observations including: (i) failures to thoroughly investigate unexplained discrepancies or batch failures; (ii) several deviations associated with HEPA (high-efficiency particulate absorbing) filters used in manufacturing; (iii) failure to establish written procedures for production and process control; (iv) the non-establishment of validation designed to prevent microbial contamination of the sterile drug product; (v) inadequate written procedures to prevent contamination; (vi) standard operating procedures that were not followed or were deficient; and (vii) equipment and facilities used in the manufacture of drug product were not adequately maintained or appropriately designed to facilitate operations for their intended use by Catalent.

65. According to the Form 483, inspectors examining historical operational data found the system on one filling line at the plant had failed repeatedly between 2017 and 2021, leading to sterility being "compromised" in the area where drug products were being manufactured. Other GMP manufacturing areas had a similar elevated level of HEPA filter failures with the root cause of the HEPA filter failures unknown. As the Form 483 stated: "Your firm failed to ensure your investigations identify appropriate root causes and you failed to implement sustainable corrective action and preventive action (CAPA)." In addition, Catalent

[13] This Form 483 was made public the week of January 18, 2022.

staff had repeatedly (yet improperly) classified the failures of the air-filtration system as "minor" in internal records at the plant.

66. Due to the severity of these issues identified in the October 2021 Form 483s, from November 2021 through summer 2022, Catalent shut down the Brussels facility's filling operation to remediate the issues.[14]

67. Due to the shutdown, on December 17, 2021, Novo Nordisk announced: "A contract manufacturer filling syringes for Wegovy pens for the US market has temporarily stopped deliveries and manufacturing following issues with Good Manufacturing Practices. As a consequence, Novo Nordisk does not expect to be able to meet demand in the US in the first half of 2022 and few new patients are expected to be able to initiate treatment."[15] Indeed, throughout 2022, shipments of Wegovy were delayed as Catalent addressed problems raised by the FDA's inspection of the Brussels facility. According to media reports, Novo Nordisk's Chief Financial Officer Karsten Munk Knudsen was quoted as saying that, "in hindsight, the company may have made a mistake in choosing Catalent and was now tightly overseeing the firm's filling operations of Wegovy in Brussels."[16]

(b) Brussels Facility: August 2022 Form 483

68. The FDA conducted a second inspection at the Brussels facility from August 10-19, 2022. On August 19, 2022, the FDA issued another Form 483 detailing continuing problems with air filtration and other equipment-related issues at the Brussels facility.

---

[14] *Reuters*, Wegovy weight-loss injection factory plagued by sterile-safety failures.

[15] Dan Stanton, *Catalent hit with FDA 483 at Belgian fill and finish facility,* BIOPROCESS INTERNATIONAL, (Jan. 7, 2002), https://bioprocessintl.com/bioprocess-insider/regulations/catalent-hit-with-fda-483-at-belgian-fill-and-finish-facility/.

[16] Maggie Fick, *Insight: Wegovy weight-loss injection factory plagued by sterile-safety failures* (July 27, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/wegovy-weight-loss-injection-factory-plagued-by-sterile-safety-failures-2023-07-27/.

69. The August 2022 inspection found new problems with air quality in sterile areas had cropped up since the October 2021 visit. "Inspectors on both visits found Catalent staff were not performing required safety controls, with breaches including failing to regularly check that equipment was not contaminated with microbes." FDA inspectors said the lapses at the Brussels plant "represented the most serious form of violations . . . which show Catalent shut the facility down twice between the two inspections."

70. "In November 2022, the FDA published a final decision on the findings that allowed the [Brussels] Facility to remain open", while it remediated the sterilization issues.

71. According to a July 27, 2023 report by *Reuters*:

> The FDA reports do not say how many filling lines were inspected or what drugs were being manufactured on the lines examined. Four regulatory experts and two former FDA inspectors who reviewed the documents told Reuters the findings raised concerns about the safety of all manufacturing being done at the factory, including for Wegovy.
>
> "Based on the FDA's findings, I would be concerned about the sterility of the products made at this site," said Susan Bain, an assistant professor of regulatory and quality sciences at the University of Southern California and former FDA inspector.
>
> * * *
>
> In both visits, the FDA inspectors found Catalent staff had repeatedly failed to investigate why equipment was malfunctioning. They found the facility didn't have adequate written procedures for performing tests to prevent microbial contamination during manufacturing.
>
> The 2022 inspection found the factory didn't have appropriate controls to ensure data files for quality-control instruments were protected from the risk of manipulation.

2. Bloomington, Catalent's Top Biologics Manufacturing Facility, Is Also a Repeat Recipient of Multiple Form 483s

72. Catalent's manufacturing facility in Bloomington, Indiana also had repeated run-ins with the FDA. In 2018 and 2019, the FDA found "objectionable conditions" at the

Bloomington facility.[17] In 2018, those conditions included "an unacceptably high number of mold recoveries used in the classified rooms" used for the manufacture of an undisclosed bulk drug substance and "a lack of quality oversight in the review of records and procedures followed in drug substance manufacture, inadequate procedures in place to avoid deviations from reoccurring, and insufficient controls to prevent unauthorized changes to data[.]"[18]

73. The Bloomington facility received an additional Form 483 from the FDA in 2020 from an inspection conducted from August 27, 2020 through September 2, 2020, which cited, among other things: (i) "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and/or followed[;]" (ii) "[y]ou do not always follow good aseptic techniques . . . for the manufacture [of] . . . Drug Product[;]" and (iii) other violations of sterilization and sanitization procedures.

(a) Bloomington: September 2022 Form 483

74. During the Class Period, the FDA conducted an inspection at the Bloomington facility (from August 1, 2022 to September 1, 2022). On September 1, 2022, the FDA issued a Form 483 pursuant to this inspection, which identified twelve (12) problems at the facility including, without limitation, finding foreign matter, particulate matter, and foreign objects and pieces in vials produced at the facility.[19] The FDA noted that the particulates had not been "adequately investigated to include an identification of the particle in the complaint sample."

---

[17] Marisa Taylor, *Special Report: U.S. rushed contracts to COVID-19 suppliers with troubled plants*, REUTERS (Dec. 2, 2021), https://www.reuters.com/world/the-great-reboot/us-rushed-contracts-covid-19-suppliers-with-troubled-plants-2021-12-02/.

[18] Dan Stanton, *Catalent clears up FDA 483 concerns at Indiana plant*, BIOPROCESS INT'L (Sept. 14, 2018), https://bioprocessintl.com/bioprocess-insider/regulations/catalent-clears-up-fda-483-concerns-at-indiana-plant/.

[19] This Form 483 was made public on or about September 20, 2022.

75. The Form 483 detailed that the FDA identified "179 occasions where particles, like black specks, foreign matter, particular matter, and foreign objects and pieces were discovered in vials produced by [Catalent]. The FDA noted in the Form 483 that the identified particles had not been 'adequately investigated to include an identification of the particle in the complaint sample,' and that 17 supplier complaints were related to stopper issues."[20]

76. In addition, the Form 483 highlighted procedural control problems, quality control issues, poor maintenance records, and inadequate laboratory controls in the manufacturing process and in the laboratory. "Specifically, the FDA mentioned equipment used in drug manufacturing that was not of appropriate design to facilitate operation for its intended use and a failure to address unexplained discrepancies in a batch of drug product."[21]

(b) Washington Post Reports on Bloomington's Sterilization Issues and Delayed Release of Vaccines Produced at that Facility

77. On September 20, 2022, the *Washington Post* released an article entitled, "FDA releasing millions of Moderna boosters as states warn of shortages," which exposed that the release of COVID-19 vaccines produced by Catalent had been delayed by regulators because of improper sterilization at Catalent's Bloomington, Indiana production facility. According to the article, the FDA had delayed the release of millions of COVID-19 vaccine booster shots filled by Catalent as a result of the poor inspection at Catalent's Bloomington facility in August 2022. FDA officials had raised concerns that vaccines packaged at the Bloomington facility could be contaminated because the facility was not sufficiently sterile.

---

[20] Millie Nelson, *Catalent hit with FDA 483 at Bloomington plant*, BIOPROCESS INT'L (Sept. 22, 2022), https://bioprocessintl.com/bioprocess-insider/facilities-capacity/catalent-hit-with-fda-483-at-bloomington-plant/.

[21] *CTLT Shares Trade Down On FDA Notice Delaying MRNA's Bivalent Booster,* UBS, (Sept. 21, 2022).

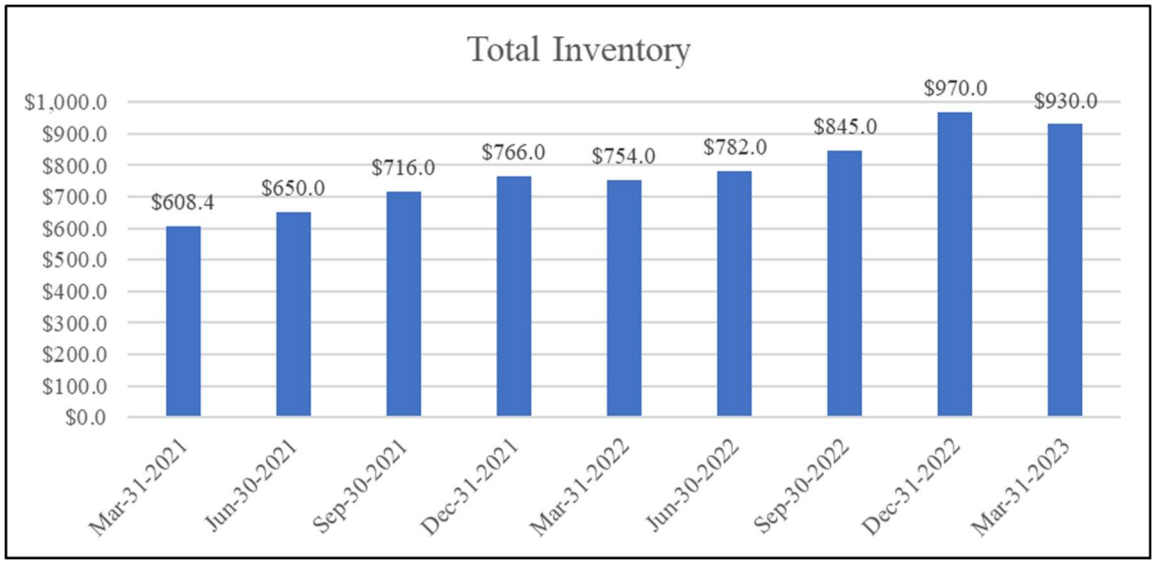
(c) Bloomington: May 2023 Form 483

78. The Bloomington facility received yet another Form 483 from an inspection conducted by the FDA from May 4, 2023 through May 12, 2023 with observations of, among other violations, a lack of written production and process control procedures, inadequate equipment revalidation, and inadequate cleaning of equipment and facilities. This Form 483 was made public on August 3, 2023.

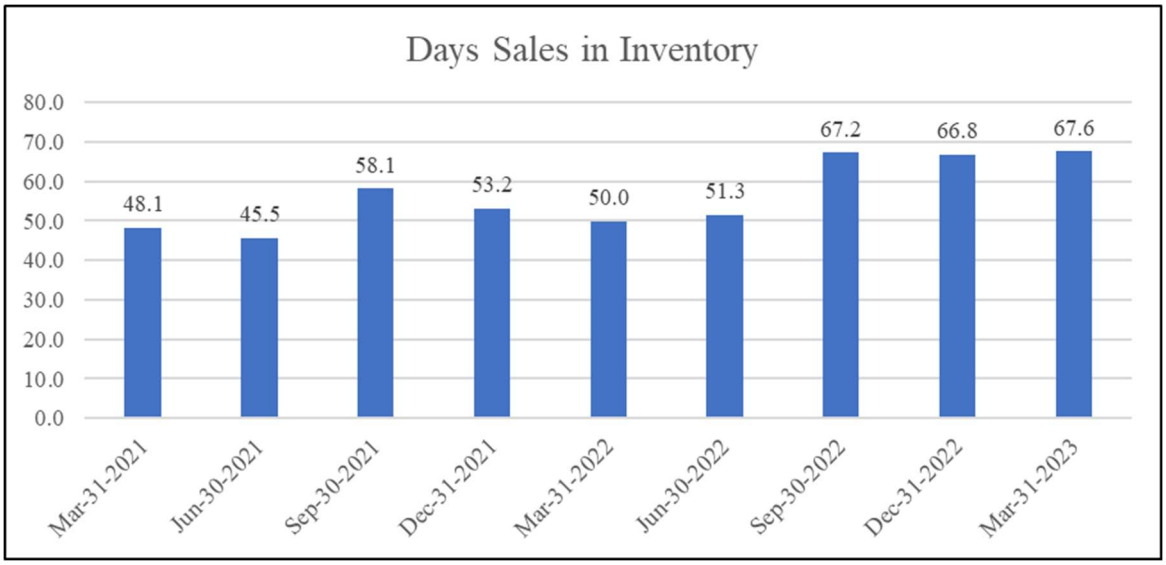
F. Catalent's False Financials – Understatement of Inventory Reserves and Improper Revenue Recognition in Violation of GAAP, and a Material Weakness in Internal Controls Over Financial Reporting

1. During the Class Period, Catalent Understated Inventory Reserves for Unsaleable Inventory in Violation of GAAP

79. During the Class Period, Catalent rapidly increased its inventory. For example, as of March 31, 2021, Catalent reported $608 million of gross inventory. By December 31, 2022, inventory had climbed to $970 million, an increase of approximately 60%. Throughout this period, approximately 80% of inventory consisted of raw materials and the remainder related to work-in-process inventory.



80. A common measure of the amount of inventory-on-hand is days sales in inventory ("DSI"): quite simply, how many days of inventory is on-hand based on the then-current level of quarterly sales. By this measure, Catalent's inventory-on-hand increased sharply beginning in the quarter ended September 30, 2022 as seen in the chart below.

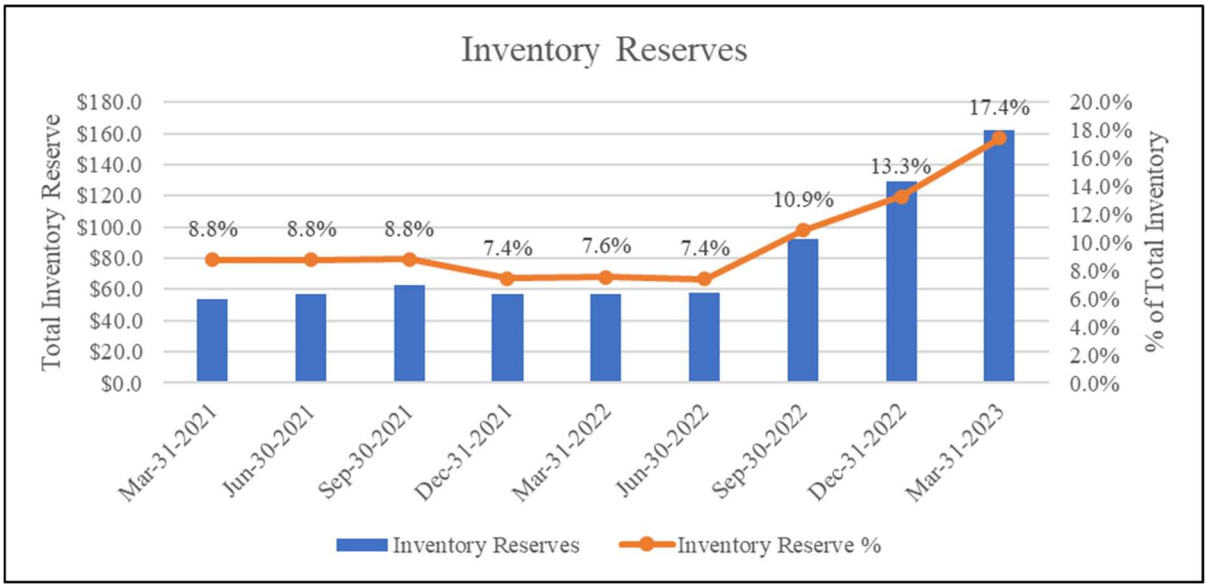


81. Initially, inventory is reported using the historical cost basis (i.e., what was the price paid to acquire the raw materials). In the event that inventory is likely to be sold for less than historical cost, GAAP requires inventory to be reported at the net realizable value (*i.e.*, lower of cost or market). Catalent's 2022 Form 10-K, states that the Company follows GAAP by recording an inventory reserve to reduce the reported value of inventory. Indeed, Catalent claims that its inventory reserve accounts for factors such as changes in customer demand and obsolescence. When Catalent increased the inventory reserve, it recorded an expense that reduced reported earnings.

82. On Catalent's November 1, 2022 Earnings Call, Defendants represented that the accumulation of inventory seen in the tables above was a strategic decision and that Catalent had deliberately accumulated abnormally high levels of inventory purportedly for positioning during

the COVID pandemic. This circumstance warranted ongoing and careful scrutiny regarding the adequacy of Catalent's inventory reserves. For example, a significant issue for Catalent was the exposure of inventory to expiration. That is, Catalent's inventory had a limited shelf life because the inventory could only be sold to the customer before its expiration.[22] Moreover, at least by May 2022, Catalent disclosed that the transition away from vaccine products was underway.[23]

83. The chart below illustrates Catalent's inventory reserve balance (blue bars), as well as the percentage of the total inventory reserved (orange line) as of each quarter from March 31, 2021 through March 31, 2023:



84. As seen in the chart above, Catalent held inventory reserves relatively static from the start of the Class Period through June 30, 2022. Of particular note is that during the fiscal year ended June 30, 2022, Catalent increased total inventory by $132 million. At the same time, Catalent increased inventory reserves by only $1 million (from $57 million to $58 million). Quite simply, while Catalent accumulated inventory, it failed to increase inventory reserves even

[22] Catalent 5/19/23 Earnings Call Tr.

[23] Catalent 5/3/22 Earnings Call Tr.

at the historical rate of approximately 8%. Not coincidentally, in each of the quarters ended December 31, 2021 (Q2 2022), March 31, 2022 (Q3 2022), and June 30, 2022 (Q4 2022), Catalent reported earnings (Normalized EPS) that exceeded consensus estimates.[24]

85. As seen in the chart below, circumstances changed in Q1 2023, ended September 30, 2022, when Catalent missed both consensus revenue and earnings targets:

	- EPS NORMALIZED -		
	CONSENSUS	ACTUAL	SURPRISE
FQ2 2022	0.83	0.90	8.43 %
FQ3 2022	0.94	1.04	10.64 %
FQ4 2022	1.15	1.19	3.48 %
FQ1 2023	0.56	0.34	(39.29 %)

86. Following Q1 2023, ended September 30, 2022, Catalent reduced its fiscal 2023 revenue guidance by approximately $350 million. Catalent identified the changing demand patterns for vaccines as an explanatory factor for this reduction.[25] Catalent also acknowledged that customer demand for new products had fallen (i.e., customers were likely to reduce future purchases of Catalent inventory).[26]

87. Consequently, at the same time Catalent had increased inventory, customers were reducing their purchases of (and need for) that inventory. This situation created a real risk that Catalent would provide concessions as an inducement to its customers to avoid incurring inventory write-downs. In other words, Catalent confronted a dual risk. On the one hand,

[24] Catalent used the term "Adjusted Net Income per Diluted Share" and S&P CapIQ used the term "Normalized EPS" for this measure.

[25] Catalent 11/1/22 Earnings Call Tr.

[26] *Id.*

Catalent had too much inventory. On the other hand, Catalent's customers already held excess product and therefore would be reducing their future purchases of Catalent's existing inventory.

88. This scenario was summed up by Defendant Castellano during the Stephens Annual Investment Conference on November 16, 2022:

> I would also say, it's a little bit of an inventory impact here on us as well. We can't control how our customers manage their supply chain and what we've learned through this October update here is some of our customers are because products aren't moving off shelves are willing to take a more -- take a different approach to how they manage their supply chain and run on lower levels of safety stock inventory than where they were. So someone like Catalent as a producer, really feels that on both ends, not only our products moving slowly off of store shelves, but you have customers with excess levels of inventory that are going to let some of that bleed in before needing to pick up demand with us.

89. An analyst from Stephens inquired when the Company expected to reduce its excess inventory position and Defendant Castellano quantified the impact of the excess inventory as approximately $400 million:

> So I would say this is an area that I would expect to improve as we get further into the fiscal year. If we're talking about what the historical level of inventory has been, it's -- we're probably about $400 million too high right now.

90. As seen in the chart above, in the quarter ended September 30, 2022, Catalent increased inventory reserves by $34 million. The increase to inventory reserves was a significant reason that Catalent's earnings missed consensus targets in Q1 2023. Yet, the increase to inventory reserves in Q1 2023 was **less** than 10% of the increase that Catalent's CFO concluded was necessary at the time. Thereafter, Catalent has increased inventory reserves from $58 million at Q4 2022 to $92 million as of Q1 2023 to $129 million as of Q2 2023 to $162 million

as of Q3 2023. This slow bleed approach has brought Catalent closer to, but remains far short of, the $400 million required reserve increase Defendant Castellano mentioned in November 2022.[27]

91. As seen in the below chart, the largest increase to inventory reserves reported by Catalent occurred beginning in Q1 2023 (September 30, 2022) and continued through Q3 2023 (March 31, 2023):

Fiscal Quarter	Catalent's Inventory Reserve	Net Increase in Reserves from Prior Quarter
Q4 2021 (ended 6/30/21)	$57 million	
Q1 2022 (ended 9/30/21)	$63 million	+6 million
Q2 2022 (ended 12/31/21)	$57 million	(-$6 million)
Q3 2022 (ended 3/31/22)	$57 million	none
Q4 2022 (ended 6/30/22)	$58 million	+$1 million
Q1 2023 (ended 9/30/22)	$92 million	+$34 million
Q2 2023 (ended 12/31/23)	$129 million	+$37 million
Q3 2023 (ended 3/31/23)	$162 million	+$33 million

92. For fiscal Q3 2023, ended March 31, 2023, Catalent disclosed an additional $55 million charge to increase the inventory reserve to account for unsaleable inventory.[28]

> In all, we expect to record a few accounting adjustments at Bloomington. One example, we expect to increase our inventory reserve by roughly $55 million related to [sustain] the raw materials and component to ensure the safety stock to minimize pandemic-related supply chain shortages. (alteration in original).

93. During Catalent's Special Call with investors disclosing this inventory reserve charge on May 19, 2023, the Company acknowledged that it had failed to apply rigor and skepticism in its business processes such as inventory reserve-setting:

[27] The Company parted ways with CFO Castellano on approximately April 14, 2023.

[28] The $55 million increase was recorded as a charge to earnings in Q3 2023 and an increase to the inventory reserves. As compared to Q2 2023, the inventory reserve at the end of Q3 2023 increased by a net amount of $33 million due to other activity in the period such as write-offs of previously reserved inventory.

> To recap, we have reviewed the procedure with which we execute our precise processes to determine how macro events impacted our ability to meet our forecast. After delivering 3 years of exemplary performance, we are bringing back more rigor and skepticism, such as known and previously unforeseen macro and internal operations drivers.

94. Thus, Catalent acknowledged that a lack of rigor and skepticism as observed through the inventory reserve-setting process contributed to its earnings performance through Q4 2022 (ended June 30, 2022). During that time, while Catalent knowingly accumulated excess levels of inventory with exposure to expiration precisely as customer demand for vaccine products waned, it failed to adjust the stagnant levels of inventory reserves.

95. While Catalent has nearly tripled inventory reserves thus far in fiscal 2023 (ended June 30, 2023), it failed to do so either timely (*i.e.*, in Q1 2023) or in the amount identified as required by its then-CFO (*i.e.*, to $400 million). As seen in the chart above, Catalent's days sales in inventory ("DSI") as of March 31, 2023, remains elevated relative to historic levels. To reduce current DSI of approximately 67 days to the same DSI during fiscal 2022 of approximately 52 days, Catalent would require a further increase to inventory reserves of at least $175 million.

2. Catalent Recognized Revenue in Violation of GAAP

(a) Catalent's Revenue Recognition Practices on Customer Contracts

96. Catalent applied ASC 606, *Revenue from Contracts with Customers*, as the GAAP standard to determine revenue recognition. (2022 Form 10-K, at 78) Using this standard, Catalent recorded revenue each period based on the total transaction price that it anticipated receiving from each customer in consideration of the extent of its obligations that it had satisfied to the customer (*e.g.*, delivery of products).

97. Catalent allowed its customers to modify their contracts. A contract modification is a change in the scope or price (or both) of a contract. (FASB ASC 606-10-25-10.) When a

customer contract was modified, Catalent updated its estimate of the transaction price. (2022 Form 10-K, at 88.) Specifically, at the time of the modification, Catalent compared the cumulative amount of revenue that it had recognized from the contract to the modified transaction price eligible for recognition and recorded an adjustment in the current period to correct the total. (*Id.*)

(b) Catalent Restates Improperly Recognized Revenue for Q4 2022 (Ended June 30, 2022)

98. On May 8, 2023, Catalent confirmed that it had identified an accounting error that required correction of its fiscal year 2022 financial statements. Catalent had violated ASC 606 when it improperly accounted for a customer concession. The error resulted in a $26 million overstatement of earnings before income taxes in Q4 2022 and reduced previously reported Adjusted EBITDA by 7% and reduced Adjusted Net Income and Adjusted Net Income per Share by 12% each. ***Indeed, Catalent's restated financials show that, but for the improper revenue recognition, Catalent would have missed even the low end of Wall Street earnings guidance provided for Q4 2022—a hallmark of financial statement materiality***. Consequently, the error was material to Catalent's financial statements for Q4 2022. (ASC 250-10-S99, Materiality).

99. As corrected, Catalent would have missed consensus earnings targets using any of these metrics: (in $ millions except per share amounts)

	Q4 2022 Adjusted EBITDA	**Q4 2022 Adjusted Net Income**	**Q4 2022 Adjusted Net Income per Share**
Consensus Estimate	$376.2	$208.2	$1.15
As Reported	$384.0 Beat	$215.0 Beat	$1.19 Beat
As Restated	$358.0 Miss	$189.0 Miss	$1.05 Miss

3. Material Weakness in Catalent's Internal Controls Over Financial Reporting for Fiscal 2022 Ended June 30, 2022

(a) SEC Rules

100. Federal law requires that the CEO and CFO of public companies certify their company's quarterly and annual reports filed with the SEC and the procedures established by those companies to prepare the financial statements and disclosures.

101. Section 302 of the Sarbanes-Oxley Act of 2002 (or "SOX"), 15 U.S.C. § 7241, was designed to ensure that a public company's CEO and CFO take a proactive role in their company's public disclosures and to instill investors with confidence concerning the accuracy, quality, and reliability of a company's periodic SEC reports. SOX requires that the CEO and CFO of a public company address the following topics in annual SEC filings (a Form 10-K for Catalent): (1) the material accuracy and fair presentation of the report's disclosures; (2) establishment and maintenance of disclosure controls and procedures ("DCP"); and (3) any material changes to the company's internal controls over financial reporting ("ICFR"). The CEO and CFO must certify that: (1) they have reviewed the periodic report; (2) it does not contain any untrue statement of material fact or omit to state a material fact necessary to make any statements made not misleading; (3) based on their knowledge, the financial statements and other financial information fairly present the financial condition and operations of the company; (4) they have maintained disclosure controls and internal controls and have designed such controls to ensure that all material information is made known to them and to provide reasonable assurance regarding the reliability of financial information; and (5) they have disclosed to the audit committee and auditors all significant deficiencies and material weaknesses in the design or operation of internal controls. These certifications communicate to investors that all material information required to be disclosed is contained in the report.

102. Section 404 of SOX, 15 U.S.C. § 7262, requires management of public companies such as Catalent to establish and maintain a system of internal controls relating to, among other things, financial reporting. Section 404 further requires management to document, test, and maintain those controls and procedures to ensure their effectiveness, as well as to assess and report on the design and operating effectiveness of internal controls over financial reporting on an annual basis. Ultimately, Section 404 requires that management of a public company annually evaluate the effectiveness of the company's internal control over financial reporting and disclose the conclusion, including any identified material weaknesses, to investors.

103. Section 404 of SOX was "intended to bring information about material weaknesses in [internal controls] into public view." SEC Release No. 33-8810, at 38. Under Item 308 of Regulation S-K, 17 C.F.R. § 229.308(a)(3) (2017), "[m]anagement is not permitted to conclude that the registrant's internal control over financial reporting is effective if there are one or more material weaknesses in the registrant's internal control over financial reporting." A statement that ICFR are effective is, therefore, an assertion by management that there are no material weaknesses in such internal controls.

104. The COSO Framework states: "[i]nternal control is a process, effected by an entity's board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives" relating to (i) effectiveness and efficiency of operations; (ii) reliability of financial reporting; and (iii) compliance with applicable laws and regulations.[29]

[29] "COSO refers to The Committee of Sponsoring Organizations of the Treadway Commission," an organization that develops guidelines for businesses to evaluate internal controls, risk management, and fraud deterrence. In 1992 (and subsequently re-released in 2013), COSO published the Internal Control – Integrated Framework, commonly used by businesses in

Footnote continued on next page

105. COSO identifies five interrelated components of internal control: (i) control environment; (ii) risk assessment; (iii) control activities; (iv) information and communication; and (v) monitoring activities. COSO requires that: "[e]ach of the five components of internal control and relevant principles is present and functioning [and that] [t]he five components are operating together in an integrated manner." COSO also identifies that these components are relevant to an entire entity and to the entity level, its subsidiaries, divisions, or any of its individual operating units or functions.

106. A deficiency in ICFR may pertain to either a deficiency in 1) design or 2) operation of a control. (SEC Release No. 33-8810 § I, at 4-5.) A design deficiency "exists when (a) necessary controls are missing or (b) existing controls are not properly designed so that, even if the control operates as designed, the financial reporting risks would not be addressed." (SEC Release No. 33-8810 § II.A.1.b, at 15 n.29.) An operating deficiency exists when a properly designed control does not operate as designed, or when the person performing the control does not possess the necessary authority or competence to perform the control effectively. (SEC Release No. 33-8810 § II.A.2, at 21.)

107. A company's DCP and ICFR cannot be considered effective if a "material weakness" exists. A "material weakness" in ICFR is "a deficiency, or a combination of deficiencies, in [internal control over financial reporting] such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis." (SEC Release No. 33-8810 § II.A, at 9.) Likewise, a material weakness in DCP arises when there is a reasonable possibility that the

---

the United States to design, implement, and conduct systems of internal control over financial reporting and assessing their effectiveness.

company's controls will fail to timely prevent or detect a material misstatement in a public disclosure.[30] A reasonable possibility arises when the chance of a future event occurring (*e.g.*, a material misstatement) is more than slight. (SEC Release No. 33-8810 § II.B, at 34 n.47.)

108. Ultimately, prior to making the SOX certifications, Catalent management was required to conduct an appropriate evaluation of internal control. In doing so, the SEC expected management's evaluation to focus on "areas of weakness or continuing concern."[31] This is because the "required evaluation should help to identify potential weaknesses and deficiencies in advance of a system breakdown, thereby ensuring the continuous, orderly, and timely flow of information within the company and, ultimately, to investors and the marketplace."[32]

(b) Catalent Restates Its Previously Issued SOX 404 Opinion as of June 30, 2022

109. As described herein, Catalent filed its original Form 10-K on August 29, 2022. Therein, Catalent disclosed its conclusion that ICFR was effective as of June 30, 2022 based on the criteria established by the 2013 COSO Framework. (Catalent 2022 Form 10-K, p. 129.) This disclosure asserted that Catalent did not have any material weaknesses at that time.

---

[30] The SEC has noted that ICFR is a subset of DCP. *See* SEC Final Rule, *Certification of Disclosure in Companies' Quarterly and Annual Reports*, Release No. 33-8124, 17 C.F.R. Part 228, at *4, 9 (2002). ("these procedures [relating to DCP] are intended to cover a broader range of information than is covered by an issuer's internal controls related to financial reporting"). Thus, a material weakness in ICFR demonstrates a material weakness in DCP.

[31] *Mgmt.'s Report on Internal Control Over Fin. Reporting & Certification of Disclosure in Exchange Act Periodic Reports*, SEC Release No. 33-8238 § II.E., 68 Fed. Reg. 36636 (Aug. 14, 2003) "While the evaluation is of effectiveness overall, a company's management has the ability to make judgments (and it is responsible for its judgments) that evaluations, particularly quarterly evaluations, should focus on developments since the most recent evaluation, areas of weakness or continuing concern or other aspects of disclosure controls and procedures that merit attention."

[32] SEC Release No. 33-8124 § VII, 17 CFR Part 228, at *17.

110. On June 12, 2023, however, Catalent disclosed that its previously issued SOX 404 certification had been made in error. In fact, a material weakness had existed as of June 30, 2022, but Defendants failed to disclosed it that time. Catalent belatedly disclosed the material weakness as a result of the Company's reversal of revenue for Q4 2022:

> Due to the discovery of this error, Catalent also re-evaluated the effectiveness of its internal control over financial reporting ('ICFR') as of June 30, 2022 and identified a material weakness in its ICFR as of that date related to the accounting for modifications of customer agreements at our Bloomington, Indiana facility.

111. Accordingly, Catalent restated its SOX 404 report on ICFR as of June 30, 2022 as follows:

> In Management's Annual Report on Internal Control Over Financial Reporting included in the Original Form 10-K, management, including our Chief Executive Officer and our Chief Financial Officer, concluded our internal control over financial reporting was effective as of June 30, 2022. Management subsequently concluded that the material weakness described above existed as of June 30, 2022. As a result, management has concluded that we did not maintain effective internal control over financial reporting as of June 30, 2022 based on the criteria in *Internal Control-Integrated Framework (2013 version)* issued by COSO. Accordingly, management has restated its report on internal control over financial reporting.

112. The specific internal control breakdown identified by Catalent relates to revenue recognition from customer agreements. Management claimed that this issue originated at its Bloomington facility. At this location, Catalent did not have sufficient personnel with adequate knowledge of the requirements of ASC 606 to recognize revenue in such a way that a material misstatement could be detected or prevented on a timely basis. To remediate this material weakness on a prospective basis, Catalent was forced to hire additional technical accounting resources both at Bloomington and at corporate, as well as require additional training for the Executive Leadership Team ("ELT") and other critical customer-facing personnel.

4. Breakdown of Operational and Engineering Controls at Catalent's Manufacturing Facilities Further Demonstrates Weaknesses in Catalent's Internal Controls

113. The unmonitored breakdown of Catalent's revenue recognition-related internal controls at its Bloomington facility was not an isolated incident. During fiscal 2023, Catalent also experienced breakdowns of its operational and engineering controls at that facility.[33] In response to these breakdowns, Catalent was forced to make management changes. These control deficiencies also caused Catalent to reduce fiscal 2023 net revenue and Adjusted EBITDA guidance by more than $400 million.[34]

G. Confidential Witnesses

114. Former Catalent employees and others with knowledge confirm, among other things: (i) repeated GAAP violations by Catalent, including improper recognition of revenue on sales concessions; (ii) fictitious journal entries being made by senior executives to make Catalent's financial results appear stronger than they were; (iii) failure to properly reserve for bad debt, including for old and uncollectible invoices; (iv) weaknesses in internal control over financial reporting, including with Catalent's inventory tracking methodology and inventory documentation (or lack thereof), and a failure to timely write off significant amounts of inventory that was unused, expired, unsaleable, or even unaccounted for; (v) safety cutbacks and serious deviations from SOPs; (vi) severe quality control issues at the Bloomington, Brussels, and Harmans/BWI facilities, which resulted in repeated FDA violations for the two facilities producing commercial products; (vii) a constant push by Catalent's senior management to keep

[33] Press Release, *Catalent Provides Business Update & Names Ricky Hopson as Interim Chief Fin. Officer* (April 14, 2023).

[34] *Id.*

manufacturing product despite "major quality issues" in order "to meet revenue deadlines;" and (viii) "no [other] business in the pipeline" once the vaccine business slowed.

115. These witnesses also provide factual support for a strong inference of scienter on Defendants' part regarding the false and misleading nature of their statements and omissions during the Class Period.

1. Witness Descriptions[35]

116. CW-1 was a former Senior Accounting Executive at Catalent's Harmans, Maryland facility from summer 2022 through the end of the Class Period. According to CW-1, he reported to Sharad Dubey (Senior Director of Finance and Accounting Cell and Gene Therapy) who reported to Jesse Boyd (Vice President of Finance, Cell, Gene and Protein Therapies) who reported to then-CFO Tom Castellano. CW-1 had a team of people reporting to him and oversaw accounting and finance functions.

117. CW-2 was a former Finance Accounts Receivable Manager contracted by Catalent vendor and consulting firm, Practus, to work at Catalent's Harmans facility from June 2022 to November 2022. According to CW-2, he was contracted to fill in for Cindy Wyle as Finance Accounts Receivable Manager, while Wyle was focused on helping Catalent migrate their ERP system. CW-2 reported to Martina Nielsen (Senior Finance Manager) who reported to Sharad Dubey (Senior Director of Finance and Accounting, Cell and Gene Therapy) who reported to Jesse Boyd (Vice President of Finance, Cell, Gene, and Protein Therapies) who reported to Catalent's CFO, Tom Castellano. CW-2 had a team of four (4) people who reported

[35] Plaintiffs believe that the details of the responsibilities of all of the CWs contained herein are sufficient to satisfy the requirements of the PSLRA. However, Plaintiffs can provide additional specificity, including exact titles for CW-1, CW-3, CW-6, CW-7, CW-8, CW-10, and CW-12 to the Court through an *in-camera* submission.

to him. According to CW-2, part of his responsibilities included working on "cash flow receivables" and project billing. CW-2 explained that he has more than thirty (30) years of experience in accounting, across many different fields, including the pharmaceutical industry, and advised that he previously worked at another pharmaceutical company.

118. CW-3 was a former Senior Director at Catalent in Maryland, before the Class Period until the fall of 2021. CW-3's responsibilities while at Catalent, included oversight responsibilities and CW-3 had direct interactions with Catalent's larger clients at the Harmans/BWI facility. CW-3 ultimately reported up to Manja Boerman (President, Cell and Gene Therapy) and by the end of CW-3 tenure in the fall of 2021, the majority of revenues for Catalent's cell and gene therapy were generated by the Company's Harmans/BWI facility.

119. CW-4 was employed at Catalent's Bloomington, Indiana manufacturing facility in several positions from August 2020 to March 2023. CW-4 was a: (i) Production Analyst from May 2022 to March 2023; (ii) Production Trainer from May 2021 to May 2022; and (iii) Senior Manufacturing Associate from August 2020 to May 2021. According to CW-4, his direct supervisor was Mark Boetjer, who reported to current Director, Drug Product Manufacturing, Sophia Percival, and Nolan Weslick.[36] CW-4 noted that Percival and Weslick reported to the Director of Operations. CW-4 explained that while working in manufacturing, he worked primarily on the flex line, manufacturing syringes, vials, and cartridges until his promotion to Production Trainer, after which he trained the operators responsible for manufacturing these items. CW-4 added that his work included producing the COVID-19 vaccine for Moderna and explained that he was aware of what was being produced, because he was familiar with client numbers and what the corresponding products were.

[36] CW-4 could not confirm the spelling of either Boetier or Weslick's last name.

120. CW-5 was a former Manufacturing Operator at the Company's Bloomington, Indiana facility from March 2021 to June 2022. CW-5 reported to Mark Belchier, who CW-5 described as the Manufacturing Supervisor of syringe and vial production at Bloomington's Building-A. CW-5 recalled that Belchier replaced an Operations Manager named Nolan Weatherneck,[37] who had transferred to another role at Bloomington. According to CW-5, both Belchier and Weatherneck reported to Sophia Percival (Director, Drug Product Manufacturing) who reported to a Director of Operations (name not recalled), who reported to Arturo Lopez (Senior Director of Human Resources at Bloomington). CW-5 recalled that Arturo Lopez took over leadership of the Bloomington facility in Summer or Fall 2021. CW-5 was involved in on-the-job training at Building-A and described himself as the "go-to person" for SOPs because he learned them "inside-and-out" and he "knew them by heart."

121. CW-6 was employed at Catalent's Brussels, Belgium facility from before the Class Period to end of year 2021. CW-6's most recent position was in project management where he reported to SLT (site leadership team) director who reported to general manager Wim Blendeman who reported to Vice President Operation Drug Products Biotherapeutics Barbara Sambuco.

122. CW-7 was a former operations and customer service manager at Catalent's Brussels facility from Summer 2021 – Summer 2022. In CW-7's final reporting structure, he reported to Clément Sibert (Supply Chain Director) who reported to Wim Blendeman (General Manager, Brussels facility), who reported to someone (name not recalled) who reported to then COO-Alessandro Maselli. CW-7 advised that his responsibilities included forecasting production plans for the Brussels facility 18 months ahead and updating this information monthly.

[37] CW-5 could not confirm the spelling of Weatherneck's last name.

123. CW-8 was a former senior level employee on the Company's finance team from before the Class period to the Fall of 2021. At the end of his tenure, CW-8 reported to Larry Shapiro (Vice President – Head of Global Tax and Treasurer) who reported to then-CFO Tom Castellano. CW's responsibilities included GAAP details from corporate controllership and working with the "top side" numbers for tax reporting purposes.

124. CW-9 was a former Manager of Business Analytics at Catalent's Somerset, New Jersey headquarters from August 2018 to September 2022. According to CW-9, in his final reporting structure, he reported to Global Op Ex Leader, Victoria Caporaso, who reported to Global Head of Business Process Improvement, Joanne Humble, who reported to Senior Vice President, Enterprise Functions, Chief of Staff Kay Schmidt, who reported to then-COO Alessandro Maselli. CW-9 advised that his responsibilities included building out Catalent's dashboard and extracting information and Key Performance Indicators ("KPI") from the dashboard to compile and put into a PowerPoint Presentation to be reviewed by the Company's Executive Committee (as known as the Executive Leadership Team) at the monthly closing meetings.

125. CW-10 was a former sales representative supporting the Bloomington, Indiana facility from before the Class Period and through calendar Q4 2022. According to CW-10, the entire sales team reported Hamid Farzad (Head of Drug Product North America) who was responsible for all drug product manufacturing sales in North America. CW-10 stated that Farzad reported to Alessandro Maselli.

126. CW-11 was employed in several Quality Assurance roles at Catalent's Bloomington, Indiana facility from October 2020 through July 2023 including as Senior Quality Assurance Representative and Quality Assurance Supervisor (for his last year at the Company).

127. CW-12 was part of the Harmans Manufacturing Management Leadership Team from August 2019 to July 2021. CW-12 explained that at Harmans, manufacturing operations were split up into multiple suites based on client. CW-12 noted that his day-to-day responsibilities as part of the Harmans Manufacturing Management Leadership Team were running manufacturing and leading investigations into deviations and contaminations at the Harmans facility.

128. CW-13 was a former Principal Validation Engineer at the Company's Bloomington, Indiana facility from March 2022 to June 2023. CW-13 stated that he had previously been employed by Cook Pharmica from September 2006 to October 2017 and that he became a Catalent employee when Catalent acquired Cook's Bloomington facility. CW-13 left Catalent in March 2019 to go back to work for Cook Pharmica until he rejoined Catalent in March 2022. According to CW-13, in June 2023, he reported to Senior Validation Supervisor Jaret May, who reported to Senior Validation Manager Amanda Siewert, who reported to Director QA Validation Tim Miller. CW-13's department's responsibilities included validating processes and procedures including confirming that employees were cleaning laboratory rooms and machinery according to written procedures.

2. Witness Accounts

(a) Quality Control Issues and SOP Deviations Prevalent at Catalent's Top Production Facilities Throughout The Class Period

129. Catalent's rapid expansion of manufacturing activity at the Bloomington, Brussels, and Harmans/BWI production facilities, hyper-focus on production speed over quality, and significant SOP deviations led to serious regulatory problems for the Company. Former Catalent employees and contractors at the Bloomington, Brussels and Harmans/BWI facilities confirm: (i) severe quality control issues at all three facilities which resulted in repeated

regulatory FDA violations, internal SOP deviations, and unsterile and unsafe conditions; (ii) a constant push by Catalent's senior management including the Individual Defendants to keep manufacturing product despite "major quality issues" in order "to meet revenue deadlines;" and (iii) consistent complaints by large customers including Sarepta and AveXis for Catalent to stop producing their products so quickly.

(1) Bloomington Facility

130. CW-13 confirmed that deviations in controls and procedures and the consequences and results of those deviations were entered into the Company's TrackWise database, assigned a Deviation number, and tracked.

131. According to CW-4, anyone who had taken the "PathWise" class had access to TrackWise and could see the deviations, where they occurred, and initials noting who had submitted them. CW-4 confirmed that C-Suite executives at Catalent had access to TrackWise, if they had completed the course or been "grandfathered in." CW-4 explained that in order to be "grandfathered in," executives had to make a request to the training department to be granted that status.

132. CW-4 confirmed that former CEO John Chiminski visited the Bloomington site "on and off" during his employment. CW-4 confirmed direct interactions with former CEO John Chiminski during his visits. Staring in May 2022, CW-4 attended meetings for each shift referred to as "Tier 2" and "Tier 3" Meetings. According to CW-4, these meetings took place each morning and included a discussion of the SOP deviations observed over a weekly period and what was going on in manufacturing. According to CW-4, he believed the CEO, CFO, and other executives had access to and utilized TrackWise because they referenced information contained in Trackwise during the Tier Meetings.

133. CW-13, Principal Validation Engineer at the Company's Bloomington facility from March 2022 to June 2023, recalled particulates being found by the Company in vials throughout his tenure.

134. CW-4 recalled deviations from SOPs were an issue at the Bloomington facility throughout his tenure (August 2020 – March 2023), with violations occurring daily. CW-4 advised that he had several arguments with management and his supervisors regarding the handling of SOPs. According to CW-4, Mark Boetjer, Nolan Weslick, and Nikki Reder in management were aware of the SOP violations and CW-4 was aware of individuals reporting deviations to them. CW-4 explained the deviations were overlooked and ignored by everyone at Bloomington, including Quality Assurance. CW-4 stated that Quality Assurance "quite frankly" did not care about adhering to the rules and regulations set forth in the SOPs. CW-4 added that this was especially true regarding sanitation rules.

135. CW-5 confirmed that there were many deviations of SOPs at Building-C of the Bloomington facility, because much of their staff was inexperienced and not well trained in working with syringes/injectables in the pharmaceutical manufacturing industry. CW-5 explained that whenever he and Michelle Primm (Product Specialist) tried to get Building-C to follow Catalent's SOPs, they faced "big time" pushback from Supervisor Jim Hubbs. CW-5 recalled that he and Primm recorded many deviations at Building C including violations of SOP 2101042 (an SOP for high-risk intervention). CW-5 explained that because SOP 2101042 was not being followed, there was no way to ensure that operations were sterile and not contaminated. According to CW-5, this led to particulates getting into the vaccines being produced, a problem that was not fixed when his tenure ended in June 2022. CW-5 advised that Primm emailed the "chain of command" and Quality Control about the issue, but that no action

was taken to remedy the situation. CW-5 noted that deviations from SOPs became so numerous that there was eventually talk of re-doing Calatent's training program and starting again from the beginning.

136. CW-5 explained that deviations from SOPs and contaminations also occurred in Buildings A and B of the Bloomington facility during his tenure. CW-5 recalled an instance at Building-B where food particulates and blood were found floating in the Moderna vaccine. According to CW-5, the particulates and blood were found around November 2021 in "the fill" portion of the manufacturing process and explained that this was the near the end of the manufacturing process where it was going to be sent out to customers. CW-5 recalled that upon further analysis, the particulates were "lettuce, oil and vinegar, and blood," and that it was determined that the particulates did not make it into the vials.

137. CW-5 advised that Building-A would throw away contaminated batches, as per SOP, but when Mark Belchier took over at that building in the beginning of 2022, employees were instructed to not throw away contaminated batches, but rather to send them to Packaging and let Packaging handle the particulates, if they found any. CW-5 recalled that all three buildings at the Bloomington facility (A, B and C) were experiencing contamination which was occurring because SOPs were not being followed. CW-5 confirmed that every instance of contamination or particulates was supposed to be documented as were the results of the cleaning involved.

138. According to CW-5, another example of SOPs not being followed related to sign off on batch records in the production process. According to CW-5, records were falsified because employees who had not been present when the batch was produced were asked to sign-off on those batches. CW-5 also advised that managers often were trying to get him to watch

tasks that he was not qualified to be a monitor for, so that he could sign for, or be, a witness for someone signing off on a batch.

139. CW-5 stated that he noticed violations "on every shift" which he reported to Mark Belchier and/or Nolan Weatherneck. CW-5 explained that deviations caught in the manufacturing room are written up by Quality Assurance (QA) in a High-Risk Intervention Form and event log, along with the batch records. According to CW-5, any deviation from process discovered outside the manufacturing room is entered into TrackWise. He added that the number of deviations are stated in a report from TrackWise that goes to Bloomington's senior management. CW-5 explained that managers were contacted by phone for "all violations." According to CW-5, people got uncomfortable with the responses they were getting from Mark Belchier on documenting the violations, so they refused to give him the information by phone and insisted that it be done by email.

140. CW-13 also reported that the deviations were occurring at Bloomington at a steady pace during his tenure (from March 2022 to June 2023). CW-13 described Catalent's lack of success in curbing the number of deviations as seemingly taking two-steps-forward-and-three-steps-backwards. According to CW-13, the volume of deviations were of such concern at Catalent that every meeting he attended was led off by discussions of the need to improve on deviations, and what was being done to "track" those situations – which he explained meant what corrective actions were being taken to address logged deviations.

141. CW-13 described his department's daily meetings where the regular lead topic during his tenure was deviations. CW-13 recalled that the President of the Bloomington facility (name not recalled) being present for some of these meetings and discussions on deviations. CW-13 described the importance and focus on deviations as being "top-down" in that the

conversations and focus were being acknowledged and driven by Bloomington's President and senior management to personnel below them. CW-13 recalled that Bloomington's President reported to CEO Alessandro Maselli.

142. According to CW-11, as he moved to more senior positions in Quality Assurance at Bloomington, "things began to look sketchy." CW-11 explained that overall things at Catalent "did not feel right" and were not adding up. CW-11 described that he started noticing questionable things shortly after his promotion to Senior Quality Assurance Representative in August 2021 when there was a number of high-level exits including Bryce Hufford (Vice President of Quality – Biologics), and then a few months later, Anne Leonard (Head of Quality, Buildings A & B).

143. CW-11 stated that Catalent's Executive Leadership Team ("ELT") and the Site Leadership Team ("SLT") made questionable decisions following significant turnover at Bloomington. CW-11 explained that following the high-level exits, the Executive Leadership Team became more focused on Bloomington and began to take some of the responsibilities previously held by the departed members of the Site Leadership Team. CW-11 recalled Scott Gunther (current Sr. VP Quality and Regulatory Affairs) and Ricardo Zayas (current Senior Vice President Global Biologics Operations) came to visit Bloomington in November or December 2022 to meet with CW-11 regarding a proposed automated system to tracking the life cycle of a batch. CW-11 confirmed that former CEO John Chiminski visited the Bloomington facility multiple times.

144. According to CW-11 the ELT and SLT "had meetings all the time" and CW-11 was present at some following his promotion to a supervisor role in August 2022. CW-11 explained that often Scott Gunther and Ricardo Zayas were the most senior employees present at

these meetings and that current CEO Alessandro Maselli delegated a lot of tasks to Zayas. CW-11 confirmed he also began to be included on SLT email chains. CW-11 stated that everything at Catalent was "clearly not OK."

145. CW-11 recalled an SLT meeting in the Spring of 2022 where there was a discussion regarding the backlog of deviations that needed closing which resulted in Catalent bringing in a new team to assist with getting through the backlog of deviations. CW-11 added that prior to bringing in the new team, Ricardo Zayas told him there was $30 million worth of product ready to go out that was being held up due to the deviation backlog.

146. CW-11 also confirmed that Catalent was instructing employees to "push, push, push" and continue producing product and described the vibe of Catalent as "hurry up and wait." CW-11 explained that there were pushes to complete batches, but then instances of batches just sitting in the freezers for months. CW-11 recalled approaching employees to discuss mistakes or issues and being told that mistakes were happening due to long shifts and constant instruction to "push, push, push."

147. CW-11 confirmed that his managers and directors always said that the instructions to "push, push, push" were coming from above them and the Site Leadership Team appeared to just be a "middleman" for the Executive Leadership Team ("ELT"), and that this is where the instructions were ultimately coming from.

148. CW-11 explained that companies like Catalent were expected to have yearly shutdowns to perform maintenance, but Catalent "kept pushing." CW-11 noted that during his three years at Catalent, they never had an annual two-week shutdown to allow for maintenance.

149. CW-11 advised that most products had a shelf-life of 24 to 36 months, and it was odd to see batches released and still sitting in the freezer for months. CW-11 explained that

Catalent was a CDMO, but was acting as a distribution center for customers by holding their product for so long. CW-11 stated that per the customer contracts, the liability switches to the customer following production, so it was peculiar that customers were having Catalent hold onto product. CW-11 recalled asking multiple times about this and never receiving a satisfying answer. CW-11 stated that it felt like something "shady" was going on at the Company.

150. CW-11 stated that there were clients that Catalent would "bend the rules for," such as sending batches still under quarantine or allowing them to review draft batch records before Catalent's own employees had thoroughly reviewed them. CW-11 did not understand why the Company opened itself to any potential risk. According to CW-11, during a meeting in Spring 2023 with Kelly Kujan (current Senior Director of Strategy, Continuous Improvement, PMO and Training), he was venting his frustration in regard to Catalent bending the rules for certain customers and Kujan informed him that this was done for customers, such as Regeneron, who paid for batches up front. CW-11 described other issues, such as customers telling Catalent there were deviations that were not recorded and Catalent in turn saying that those may qualify as deviations for the customer, but did not for Catalent.

151. CW-11 stated that Catalent often caved to the requests and demands of the customer. According to CW-11, during the FDA's first investigation into Catalent during his tenure, in approximately August 2021, one of the notes the FDA provided was for Catalent to stop bending the rules for customers. CW-11 recalled expressing his concerns to two supervisors about how Catalent was giving too much power to customers and both supervisors informing him that the FDA had agreed with CW-11.

152. CW-11 recalled Kelly Kujan stating that it was her understanding that Moderna had allegedly stopped paying entirely or stopped paying on time once the government stopped

providing them funding for their COVID vaccine. CW-11 explained that Kujan noted that batches were finished for Moderna and had not been paid for yet.

(a) September 2022: Form 483 at Bloomington Facility

153. According to CW-4, the FDA Form 483 issued to the Bloomington facility in September 2022 had to do with particles being found in the drug product. CW-4 stated that the issues addressed during the FDA investigation and afterwards were "well-known" throughout the Bloomington facility, and that there was only an attempt to change them as a result of the FDA investigation.

154. CW-11 recalled the FDA Form-483 letters that the Company received in approximately August of 2021 and 2022, both of which focused on the Company's Aseptic practices. CW-11 stated that the FDA essentially told Catalent, "you suck at cleaning." CW-11 participated in a meeting with the FDA in approximately August 2022. CW-11 added that the next time the FDA came to Catalent after the August 2022 meeting, they noted that Catalent's cleaning was still not good enough.

155. According to CW-10, after the Form 483 issued to the Bloomington facility in September 2022, it made his job "incredibly difficult" as some customers elected not to use Catalent or were holding off working with Catalent until the issues were resolved. CW-10 explained that his sales targets became that much more challenging following the FDA investigation due to the reluctance of customers.

156. CW-9 advised that Bloomington had closed down part of their facility, perhaps one of their buildings, in response to their Form-483. CW-9 recalled seeing news about the Form 483 at Bloomington, noting that it resulted in the shutting down of a vaccine production line. CW-9 stated that the Form 483 was discussed during operational mechanism discussions which were weekly meetings run by Vice Presidents of Operations, Quality, Safety, Finance and others,

with the General Managers from the facilities, that included reviewing weekly metrics that were broken down by segment and were site specific.

(2) Brussels, Belgium Facility

157. CW-7 stated that "nothing aligned" at the Brussels facility including the warehouse, operations, SOPs and regulations. CW-7 recalled learning that contaminations were "an issue" his first day on the job (July 2021). CW-7 participated in "Ready to Execute" or RTE meetings every week where production and filling plans were discussed for the subsequent four weeks. CW advised that the General Manager of the Brussels facility, Wim Blendeman, attended around 50% of these meetings. CW-7 confirmed that he also participated in daily meetings with production and operations for planning out a few days ahead. CW advised that it was in these meetings where he learned of the "very high rate of contaminations" in Brussels' manufacturing which he described as existing during and before his tenure began.

158. CW-7 confirmed that Brussels' production on "new fillings," or new orders, "stopped immediately" in November 2021 soon after the Form-483 was issued by the FDA, while orders already in production continued to be manufactured until they were complete. CW-7 advised that full production did not fully restart by the time his tenure ended (August 2022). CW-7 recalled that after being at a full stop on new fillings for the first few months after he started, some production occurred to test for contamination in the hope that contamination issues had been resolved, but they had not been resolved. CW-7 confirmed that contamination issues had not been resolved by the end of this tenure (Summer 2022) because full production had never been restarted.

159. CW-6 explained that Lachman Consultants were hired and came on site to "assess corrective action" based on thorough research into the Brussel location's historical deviations and SOP practices. According to CW-6, Lachman Consultants is a consulting firm which

specializes in quality. CW-6 advised that Lachman stayed at the Brussels location for a long time. CW-6 advised that Scott Gunther (Senior Vice President Quality and Regulatory Affairs) was made aware of the quality issues cited by the FDA because Enrica Picardi was providing "daily updates" to Gunther as the two worked on a response to the FDA with plans to address those concerns. CW-6 described this as an "intense 30-day period" of review and updates between quality, Picardi, Gunther, and possibly Davis-Claeys, as a response to the FDA was drafted and reviewed.

160. According to CW-6 and based on conversations with former colleagues, production at the Brussels location was "shut down" for approximately one full quarter, from January to March 2022, and during that time "zero commercial revenue" was generated at the site. CW-6 confirmed that even when production was restarted, it still took a few months of starting and stopping manufacturing as they tested and awaited the results after they produced each batch. According to CW-6, Brussels generated around €80 million in revenue per year before he left in December 2021, and if manufacturing was shut down for an entire quarter with close to no money being generated, that the CFO and CEO had to be made aware.

161. CW-7 stated that in January 2022, Brussels transferred production of a few of their existing "treatments" to their sister injectables facility Bloomington, Indiana including transferring of those materials and ingredients to Bloomington. CW-7 confirmed that due to the lack of production going on at the Brussels facility from November 2021 to August 2022 (the end of his tenure), the manufacturing area was open only a maximum of 50% of the time.

162. According to CW-6, another problem that Catalent experienced was that soon after the Form 483 was issued to the Brussels facility by the FDA, some large customers said they wanted move on from Catalent. CW-6 recalled having these conversations with injectable

customers between the issuance of the Form 483 and his leaving Catalent. CW-6 advised that a U.S. pharmaceutical company was one customer who left Catalent after CW-6's tenure. CW-6 recalled that other smaller Catalent customers "built their own manufacturing capacity" in response to the shutdown at Brussels. CW-6 explained that sterility is key in the pharmaceutical industry and that customers are scared off when there are issues with sterility.

163. CW-9 confirmed that the Brussels, Belgium location was shutdown "for a long time" in early 2022 while it addressed the FDA's Form 483 issued in October 2021. CW-9 noticed from the data reported by Brussels during that time that "operational metrics" from that facility "were going down" due to the fact the site was down and therefore nothing was being produced. According to CW-9, he saw the financial reports from Brussels given his responsibilities and reiterated that those included extracted KPIs (Key Performance Indicators) from Catalent's various platforms that he accessed through the Company's dashboard.

164. According to CW-7, every month Brussels reported its various updates to Catalent's Biologics headquarters in Cham, Switzerland. It was CW-7's understanding that Cham then consolidated the information from the Biologics facilities from around the world, including Brussels and Bloomington, and then submitted their projections to corporate headquarters in Somerset, New Jersey.

165. CW-7 stated that in approximately May 2022, Pascal-Emmanuel Saint-Gelais (Head of Global Supply Chain Biologics – including Bloomington & Brussels facilities) told him that CEO John Chiminski and then-COO Alessandro Maselli were well-informed about the contamination situation at Brussels. CW-7 explained that Saint-Gelais had attended a meeting that Chiminski and Maselli had spoken at, where the details behind the contaminations and remediation efforts at Brussels were discussed.

(3) Harmans/BWI Facility

166. CW-1 explained there were quality control issues happening often at the Harmans facility. CW-1 explained that because Harmans could not release batches because of failing quality issues, the Company initiated something called Project Phoenix, which he explained was the internal name of a project to rectify the recurring quality issues at Harmans. According to CW-1, the Company brought in temporary employees to identify and propose plans to rectify the quality issues and complete the final 10% of production batches.

167. CW-3 recalled an instance when a Sarepta employee told him in a meeting that Catalent had not proven to be a reliable manufacturer and that the Company needed to stop manufacturing and fix their process, before manufacturing more of Sarepta's product.[38] CW-3 confirmed that this was mentioned multiple times during the first half of 2021. CW-3 explained that he escalated Sarepta's concern to Randy Henrickson (VP, Head of Gene Therapy). CW-3 added that complaints came from across Sarepta's project team, including the Project Manager, former Vice President, Pharmaceutical Engineering, Greg Gara, and Sarepta's quality team/group. CW-3 recalled that Sarepta's leadership reached out to Catalent and that leadership-to-leadership communications occurred, including between Manja Boerman (President, Catalent's Cell and Gene Therapy) and Sarepta's CEO [Doug] Ingram.

168. CW-3 recalled that the constant push by Catalent's senior management to continue pushing manufacturing of product occurred, even though, it was known internally that

[38] CW-3 confirmed that the Sarepta product that Catalent was producing was all for clinical trials. CW-3 added that Sarepta was Catalent's largest customer based on the number of suites the client had at Catalent. CW-3 explained that by the time his tenure ended in November 2021, the Sarepta product was in phase 3 of clinical trials and Catalent was stockpiling the product for its commercial launch.

the Company had "major quality issues." CW-3 added that "we should have stopped without them telling us" given that the quality problems were known internally at Catalent.

169. CW-3 explained that there were consistent complaints by the clients to stop producing the[ir] product. CW-3 added that the push to manufacture, despite the quality issues continued in order "to meet revenue deadlines."

170. CW-3 explained that there were quality procedures to ensure that quality issues were addressed and to get sign-off, before restarting the manufacturing process following the identification of problems. CW-3 recalled instances, where BWI's Quality Control was "absolutely bullied" by manufacturing "into going along" on restarting production, despite outstanding quality issues that had been identified and weak evidence that remediation had occurred. CW-3 described Catalent as conducting "loose" following of SOPs and that Catalent had a higher tolerance for risk, than their customers would have liked.

171. CW-3 confirmed that there were no Form 483s at Harmans/BWI because they can only be issued at sites where the FDA is inspecting commercial production.

(b) GAAP Violations Prevalent Throughout Class Period

172. Former Catalent employees and contractors confirm repeated GAAP violations by Defendants throughout the Class Period, including: (i) journal entries being made without sufficient supporting documentation, without SOX compliance, and without requisite approval; (ii) invoices or sales orders issued which violated customer contracts on how and when to bill those customers; (iii) revenue recognized in violation of ASC 606 which is the governing regulation on recognizing revenue on sales contracts; (iv) fictitious journal entries being directed to be made by senior executives to make Catalent's financial results appear stronger than they actually were; and (v) failure to properly reserve for bad debt, including for old and uncollectible invoices.

173. Former Catalent employees and contractors also confirm serious internal control issues at Catalent throughout the Class Period, including with the Company's inventory tracking methodology and inventory documentation (or lack thereof), and a failure to timely write off significant amounts of inventory that was unused, expired, unsaleable, or even unaccounted for. This resulted in Catalent billing large customers, including Sarepta, for materials those customers did not order or need. Indeed, multiple CWs confirm that a majority of the customers at Catalent's Harmans, Maryland facility were disputing their raw material invoices. Because of these disputes, customer payments were often delayed and/or needed to be partially written off or reversed through the issuance of countless credit memos. In approximately September 2022, Catalent's Audit Committee, Defendant Castellano, and others in the corporate suite were presented with the "brutal findings" of an internal audit conducted at Harmans which noted a lack of requisite experience in the finance department at Harmans, a failure of various teams at that facility to work together, and other serious control issues requiring remediation.

(1) Catalent Had No Reliable Method to Track Inventory

174. CW-1 confirmed the following issues related to Harmans' inventory: (i) Harmans had inventory that had expired; (ii) Harmans had excess inventory because certain customers had ended projects and the specific inventory could not be passed onto other Harmans' customers; and (iii) Harmans lacked a method for properly tracking inventory. CW-1 also stated that Harmans' documentation on inventory was "weak" and described Catalent's inventory tracking systems as "not sophisticated."

175. CW-2 described Catalent's inventory tracking system during his tenure as one person filling in Excel spreadsheets on raw materials with information such as when the materials arrived, quantity at any given time, and when materials were moved from one location

to another, as an example. CW-2 described it as an impossible task for one person to do in Excel and that, as a result, the inventory Excel spreadsheets were not kept current.

176. CW-1 confirmed that tracking of inventory was done manually and that Harmans had just begun experimentally tracking inventory by scanning in February 2023. CW-1 explained that because Catalent did not have a system to properly track inventory, there was a significant amount of inventory that was unused, and often, unaccounted for. CW-1 described an example involving inventory that the system indicated was in a "staging area" for 8 months, but that the material had been already used. CW-1 described this as a "persistent problem" and attributed it, in part, to poor training at the Company.

177. CW-2 confirmed that most of what Catalent bills customers for are the raw materials and components used in manufacturing their products. CW-2 explained that Catalent had a lot of raw materials in inventory that expired and could not be passed on to, or billed to, its customers.

178. CW-1 described Harmans as having an "aggressive stance on inventory," explaining that Harmans often had way too much inventory that the Company had to take a loss on. According to CW-1, often the inventory expired, or the Company only needed some of what they ordered. CW-1 advised that in both examples, the inventory costs could not be passed on to the customer. For example, CW-1 explained that Catalent had significant quantities of excess inventory ordered for AveXis and AstraZeneca and he recalled a big question at Harmans being, do they sell it, or do they write it off and throw it away. According to CW-1, it was a big charge to write it off and throw it away. CW-1 stated Catalent preferred trying to repurpose the excess inventory which CW-1 thought was an aggressive position.

179. CW-1 explained that AstraZeneca had $20 million of inventory purchased by Catalent for vaccine production that AstraZeneca did not need, which they told Harmans to keep. CW-1 stated that AstraZeneca had not paid for the inventory in question. CW-1 recalled that Sharad Dubey tried to give the AstraZeneca inventory away to colleges and non-profits, and tried to see if it could be used in the production of other Harmans customers' products. According to CW-1, the AstraZeneca inventory stayed on Catalent's shelf because they were unsure if they could get rid of it. CW-1 stated that a problem was that this inventory was very specific to the customer as it was purchased for (AstraZeneca) and could not easily be transferred to another customer.

180. CW-1 recalled Dubey telling both him and a Cost Accountant that Catalent could use excess inventory, including excess AveXis inventory, for other products. CW-1 noted that there was so much excess AveXis inventory that a new account had to be created strictly for it, for accounting purposes. CW-1 described Harmans as "out the money" because AveXis never paid for that inventory.

181. CW-2 also recalled that Catalent would try to repurpose unused and excess raw material inventory, but this was very difficult because Catalent lacked the systems to track the lifecycle of the materials. CW-2 advised that expired materials could cause contamination.

182. CW-1 explained that at the end of each year, a full physical count had to be performed by hand in order to account for everything in inventory, as opposed to a "cycle count," which he indicated would have taken place if Catalent's inventory control were more sophisticated. CW-1 stated that Catalent's external auditors could not rely upon a cycle count because of Harmans' less sophisticated inventory controls.

183. CW-1 recalled that during his tenure, Catalent switched from an older financial management system, QAD, to a JD Edwards ERP system, which he described as being Oracle-based. According to CW-1, when Catalent made the switch, "sales went way down" for more than two months at Harmans, adding that Catalent was unable to meet their customer deadlines and demands during this period which he recalled was sometime before April 2023. CW-1 added that Ernst & Young wanted to be present for the physical count during this time, given the facility's ongoing inventory issues. According to CW-1, the migration to the new ERP system "exposed" those inventory issues.

(2) Customers Disputing Payment on Raw Material Invoices

184. CW-2 confirmed that Harmans' customer invoices were created based on a milestone completion excel spreadsheet and the customer's contract. According to CW-2, invoices had to be reviewed, and if okayed, the invoices were then sent to the customers. CW-2 recalled that a spreadsheet of materials used in the batch they were being billed for was sent along with the invoice to the customer. CW-2 explained that this was where the problems occurred because customers requested supporting documentation on the life cycle of the raw materials referenced in the invoices.

185. According to CW-2, customers disputed inventory they were invoiced for because Harmans was often unable to provide reliable inventory documentation due to the facility's lack of proper procedures for tracking inventory and tracking manufacturer expiration dates. According to CW-2, customers accused Harmans of billing them for materials they did not order. CW-2 described it as a lack of proper controls on Catalent's part.

186. CW-1 confirmed that when invoices were sent out, "customers were rejecting 100% of our invoices" due to issues such as lack of proper documentation, as one example. CW-1 explained that customers were challenging Harmans for buying too many ingredients or more

than called for in the contract. CW-1 reiterated that Harmans' customers "were rejecting 100% of our invoices" in the October 2022 – December 2022 time frame.

187. CW-2 reiterated that payments by customers were often delayed, or held up, by customers because Catalent was unable to account for the life cycle of materials used in the projects because they did not have adequate backup documentation. CW-2 explained that materials billing could be up to $50 million per invoice.

188. CW-1 added that delays that Harmans experienced in receiving payment also had to do with Harmans' inability to invoice customers because batches were not being released due to quality control issues.

189. CW-2 recalled participating with Sharad Dubey (Senior Director of Finance and Accounting Cell and Gene Therapy) and Project Managers, billing personnel, and customers on five (5) or six (6) calls per week trying to collect payment on outstanding customer invoices. CW-2 recalled that the normal process was having an initial call with the customer where the customer would dispute what they were being invoiced for, usually because of a lack of supporting documentation, and then there was a follow-up call a few weeks later where Dubey would offer discounts in the range of twenty to forty percent (20–40%).

190. According to CW-2, Dubey's regular practice in these follow-up calls was to offer a large discount to the aggrieved customer, as an example, if the customer agreed to accept the documents that were submitted and to make payment, and Dubey stating to CW-2 that he (Dubey) just needed to "keep the cash flow going." CW-2 recalled Sharad Dubey saying to customers on more than one occasion that he (Dubey) had the authority to offer the settlements and that he was willing to take the "significant hit" so that the customer would stay with Catalent. CW-2 explained that the Director of Project Managers and the Vice President of

Operations also were present on the initial calls if they were dealing with a large customer, but that Dubey was the most senior person on the calls where he offered the customer a settlement. CW-2 explained that the customers often agreed to the deal, which CW-2 described as like "a gentlemen's agreement" that was done verbally or by handshake, with no documentation about the deal or discount that had been agreed upon.

191. CW-2 recalled one customer in particular being "so exasperated with operations" that in one of these calls the customer stated that he could not understand how a multi-billion company like Catalent could not account for such things as lifecycle of inventory, sales orders, and purchase orders. CW-2 also recalled that other customers made similar types of statements.

192. CW-2 advised credit memos were issued in order to offer a reconciliation on what Catalent had offered as a discount or settlement with the customer.

193. CW-1 recalled outside auditor Ernst & Young, and Catalent's internal audit team, asking why there were so many credit memos issued, and CW-1 explaining that many credit memos had to be issued to reverse invoices that customers were challenging.

194. CW-1 confirmed that Harmans had around 50 customers including Sarepta and AveXis, but that "it was really only Sarepta" because Sarepta was, by far, the largest account for Harmans.

195. CW-2 advised that Sarepta was one of the customers complaining about and refusing to pay for products they did not order. CW-2 noted that Sarepta was given discounts by Sharad Dubey in order to get some payment without proper supporting documentation. CW-2 described Sarepta as one of Catalent's only customers "keeping [Catalent] alive" because the accounts receivables with other customers "were in bad debt." According to CW-2, Sarepta wanted accountability for inventory when it was presented as a cost on the invoices that they

received from Catalent. CW-2 added that Sarepta rose in importance as the demand for COVID vaccines subsided. CW-2 advised that there were other customers given discounts to settle invoices, but he could not recall which ones.

(3) Revenue Recognition Delayed at Harmans/BWI Because of Project Completion and Quality Control Issues

196. According to CW-12, Harmans recognized revenue in two different ways depending on whether the product was clinical or commercial. CW-12 explained that with clinical products, depending on how the contract was written, some revenue was recognized when certain milestones were achieved, like tech transfer as an example. CW-12 explained that this was because there was risk associated with products still in the clinical phase. CW-12 added that the problem with milestone revenue recognition was that Catalent did not actually invoice the customers and get paid until the batches were released. CW-12 advised that for commercial productions, revenue was recognized when the batches were released.

197. CW-3 corroborated that for all clinical products — which were medicines that did not have full FDA approval — revenue was recognized when "milestones" were reached. CW-3 added that billing for clinical product milestones could occur during the tech transfer stage, which he explained was when the pharmaceutical client gave a product "recipe" to Catalent, and the Company first started learning how to make it. CW-3 gave the example that if a milestone was tech transfer, and that required 500 hours, once Catalent devoted those hours to learning how to make the product, it could then recognize the revenue for that work. CW-3 advised that for commercial products — which he explained were products manufactured for public consumption — revenue was not recognized until batches were completed and released. CW-3 added that for commercial products, it is a one-time revenue recognition. CW-3 recalled that

Catalent used milestone revenue recognition for roughly the first thirty (30) batches of AstraZeneca's vaccine that Catalent produced.

198. CW-1 confirmed that according to proper accounting procedures, Harmans was able to recognize revenue when certain targets and/or certain percentages of a batch was completed. According to CW-1, this was to account for the labor that was involved in reaching those targets and percentages. CW-1 explained that labor hours are estimated in the beginning of the batch's production, but that Harmans would then run a payroll report later to get the actual hours that went into creating the batch for an accurate revenue recognition.

199. CW-1 recalled that the Bloomington facility, in comparison, did not run payroll reports later on, but rather only estimated the labor used. CW-1 explained that, for example, Bloomington estimated that if 50% of the batch production process had been completed, that 50% of the labor would be estimated for revenue recognition purposes. CW-1 stated: "That's not GAAP," and described this as not accurate, auditable, or repeatable. According to CW-1, he was aware of Bloomington's practice from his conversations with Bloomington's Controller and Director of Finance, as well as Sharad Dubey (Senior Director of Finance and Accounting Cell and Gene Therapy) and Karen Santiago talking about it to him when it became a "big deal" when Catalent's "10-Q got delayed" in April 2023.

200. CW-1 stated that batches would often reach close to ninety percent (90%) of completion, so ninety percent (90%) of the revenue could be recognized, however, the final ten percent (10%) often would not be achieved because of something wrong with the batch or the related documentation, which prevented the batch from passing a quality control check. CW-1 said Catalent often could not complete that last ten (10%), and as a result, Catalent was unable to invoice the customer due to missing documentation, batch contamination, or other quality issues.

201. CW-1 explained that revenue recognition and invoicing do not, and were not, happening at the same time. CW-1 added that revenue recognition was an internal metric for Catalent and that even if 100% of the revenue was recognized, receiving payment from the customer was something different. CW-1 repeated that the invoice could not be sent to the customer until the batch was 100% completed, but that this often was not happening because of quality control issues.

202. CW-1 explained that the time difference between when Harmans could recognize revenue on percentage of completion and when it could invoice the customer for the batch was upwards of two years. CW-1 described this time discrepancy between recognizing revenue on percentage of completion and invoicing as very bad when his tenure began in August 2022, and that it remained bad when his tenure ended in early July 2023.

203. CW-1 reiterated that due to poor quality control and "sloppiness" at Harmans, with improper documentation, often-times batches had to be re-started. CW-1 described Harmans as having a "huge log jam" of batches that needed to be invoiced. CW-1 opined that Harmans was waiting to invoice $500 million dollars' worth of batches that could not be released due to missing documentation, proper procedures for recording certain information not being followed, batch contamination, or quality issues.

204. According to CW-1, Project Phoenix was implemented to get the documentation and/or labeling corrected and to get the batches completed and revenue recognized. CW-1 confirmed that Project Phoenix involved the hiring of 30-40 outside consultants to rectify these problems for the batches waiting to be invoiced. CW-1 recalled that one of these outside consulting firms was named Black Diamond.

(a) In Order to Recognize Revenue Earlier, Catalent Produces Too Fast for Customer Delivery

205. CW-3 said that Catalent "always, always" was scrambling to meet projections. CW-3 explained that the "biggest lever" to accelerate revenue recognition was always producing more for the biggest clients, such as AveXis, Sarepta, and AstraZeneca. According to CW-3 the biggest "push" came between April and July 2021, mentioning the May–June 2021 time period in particular.

206. According to CW-3, Randy Henrickson was on site at BWI and instructing manufacturing "absolutely, do not stop" and that there was "absolutely" pressure coming from former CEO John Chiminski and former CFO Thomas Castellano. CW-3 confirmed that he was given this directive by Randy Henrickson, and that he assumed this directive came from COO Alessandro Maselli. CW-3 recalled Henrickson going over the heads and the recommendations of both the BWI site General Manager and BWI Quality Control, directing the BWI head of manufacturing to "just go" and continue producing more product.

207. CW-3 advised that, at Harmans/BWI, during his tenure, Catalent produced product faster than customers wanted. CW-3 stated that Catalent was not making more product than what the contracts called for, but rather, the Company was manufacturing sooner than was needed and frequently against the clients' wishes. CW-3 explained that typically batches were held for sixty (60) to seventy-five (75) days before being released, but, at this time, they were often being held for "much longer." According to CW-3, the quality teams were unable to keep up with the amount being produced and the freezers were getting backed up. CW-3 said that Catalent needed the cash coming in, so they said were going to make the product.

208. CW-3 explained that Catalent had quality issues at the BWI site, and that the customer wanted to use the time they requested to reduce demand in order to give Catalent the

opportunity to "slow down" and address quality issues. According to CW-3, leadership, including the Suzanne Lotowycz (Senior VP Manufacturing, former VP Finance), Manja Boerman (former President, Cell and Gene Therapy), and Randy Henrickson (VP, Head of Gene Therapy) instructed the employees to "keep going, keep going," noting that Catalent had to "meet forecasts." CW-3 added that these communications primarily occurred via Microsoft Teams chat.

209. CW-3 recalled Sarepta directing Catalent to stop producing so fast, but that Catalent continued to produce Sarepta's clinical product. CW-3 added that this was because Catalent's "bottom line had to be in the black," adding that "June and July are the fiscal year," and that the biggest pushes to make product came in the final fiscal quarter leading up to that time, even when the client said to not produce anymore. CW-3 explained that there was "absolutely" direct communication from Sarepta to Catalent that came directly from their quality organization, including meetings with Catalent, an official letter, and conversations between current Sarepta CEO Douglas Ingram and former President Catalent Cell and Gene Therapy Manja Boerman. CW-3 said that the communications were from the lowest level to the top of the respective companies.

210. CW-3 explained that the same thing happened with AveXis. CW-3 specifically recalled Randy Henrickson giving the directive to manufacture more AveXis product even though AveXis did not want more products made at that time. According to CW-3, Henrickson specifically stated that this was to meet Catalent's revenue goals. CW-3 believes that Henrickson would have gotten this directive from Manja Boerman.

211. CW-3 explained that there were meetings every month between the Project Management team and finance to discuss project status and report on the percentage of

completion on all projects where that form of revenue recognition was appropriate. CW-3 recalled that PMs were instructed to "find more revenue," "find the revenue wherever you can" and that the final report went up to leadership and Castellano was on the call to review. CW-3 explained that there were various stages of reviews from low level project managers on up, with more senior meetings occurring closer to a quarter's end.

212. According to CW-3, beginning in approximately late February/early March 2021, there was a rotating member of the Executive Team at the Harmans/BWI facility each week for approximately 6 months. According to CW-3, this rotating group included: (i) then-COO Alessandro Maselli; (ii) Board Member Karen Flynn (former Chief Commercial Officer and President, Biologics); (iii) Roy Satchell (former Head of Global Strategic PMO); and (iv) the Head of Quality. CW-3 recalled Roy Satchell being present at Harmans/BWI "pretty much" every week.

213. CW-3 recalled that CEO John Chiminski and then-COO Alessandro Maselli would say to him and his colleagues at BWI "what are you doing to meet revenue targets?" as a way to push employees to meet revenue targets. CW-3 said that Chiminski and Maselli also said to do everything you can to recognize revenue. CW-3 said it was always, "revenue, revenue, revenue." CW-3 said that the push to produce and go faster in order to meet revenue targets was primarily in high volume clients including AveXis, Sarepta, and AstraZeneca.

214. CW-10, a former sales representative supporting the Bloomington facility, explained that quality control issues had an impact on the Company's approach to revenue recognition. CW-10 explained that every time a batch was discarded due to quality issues, there were difficult conversations with customers who had been billed for ruined batches. CW-10

confirmed that a number of customers were leaving Catalent because of issues around billing for ruined batches. CW-10 explained that he noticed the issues more during the second half of 2022.

(b) Catalent Manipulates Accounting to Make Up for Delays in Revenue Recognition

215. CW-2 identified the following specific GAAP violations by Catalent that he witnessed or learned through conversations he participated in with Sharad Dubey (Senior Director of Finance and Accounting Cell and Gene Therapy) and various other employees and customers of Catalent: (i) journal entries being made without sufficient supporting documentation, without SOX compliance, and without review; (ii) invoices or sales orders issued which violated customer contracts on how and when to bill those customers; and (iii) revenue recognized in violation of ASC 606 which he advised was the governing regulation on recognizing revenue on sales contracts.

216. CW-2 described Catalent's lack of proper documentation for sales orders and approval (or lack of approval) of sales orders as a big problem. CW-2 recalled that during his first week at Catalent, he was directed by Sharad Dubey to assist a team from the Company's outside auditors Ernst & Young in their testing of Catalent's internal controls over financial reporting regarding the Company's intercompany transactions. According to CW-2, he had to look into Catalent's intercompany WIP (Work In Progress) billing of "a couple of hundreds of millions of dollars," and that Ernst & Young requested supporting documentation for some of the large entries that were made. According to CW-2, the supporting documentation should have accompanied the journal entries on the intercompany WIP billings. CW-2 recalled that he then asked Senior Revenue Accountant Ben Heile for the documentation in support of those intercompany WIP journal entries. CW-2 recalled that Ben Heile's response was that he did not have any supporting documentation and that Sharad Dubey had directed him to make those

entries. CW-2 advised that he went back to the Ernst & Young auditors and said something like the supporting documentation is forthcoming which it was not. CW-2 advised that Ernst & Young did not request the documentation from him again.

217. CW-2 recalled that Ernst & Young also questioned Catalent about supporting sales orders, which CW-2 advised are necessary to generate invoices to be sent to customers for accounts receivable, because Ernst & Young found sales orders that did not match their contracts. CW-2 explained that invoices are based on the sales orders which are based on the contract and sales orders need to go through an approval process within the Company.

218. CW-2 explained that if the Catalent invoice does not match what is requested in the contract, that this can also cause problems with the customer. CW-2 explained that invoices to customers are generated from milestones reflected in the Sales Order, and that Ernst & Young brought up concerns that the milestone billing in the sales orders were not accurate. CW-2 recalled Ernst & Young advising that approval of sales orders was a "critical control function," while recalling Sharad Dubey telling CW-2 that it was "no big deal." CW-2 confirmed that he had calls with Ernst & Young to go over accounts receivable issues, and that he had the sense that Ernst & Young was frustrated with Sharad Dubey. CW-2 recalled their frustration with Dubey having to do with Catalent's lack of SOX controls around sales order approvals. CW-2 explained that he is still in contact with some of his former colleagues and subordinates at Catalent who "are crying out to him" because the accounting improprieties are continuing.

219. CW-1 said that it was his understanding that Senior Revenue Accountant Ben Heile "took the first crack" at closing revenue each month at Harmans, and then Ben would meet with the revenue managers to determine how much the numbers were missing by.

220. CW-2 attended monthly calls led by Sharad Dubey starting soon after he joined the Company in June 2022, which included other Accounts Receivable Managers, accounts receivable personnel, Project Managers, and others. CW-2 advised that Dubey led each monthly call, and that Dubey was also the most senior person on those calls. CW-2 described these month-end calls as all-hands corporate calls to "drive velocity" in closing out the month.

221. CW-2 explained that during these monthly calls, Sharad Dubey directed accounting personnel at Catalent to violate GAAP. CW-2 explained that after the "first pass" financial statements were run, Dubey directed the staff accountants to make unsupported journal entries to meet what Dubey described as "EBITDA." CW-2 explained that Dubey's unsupported journal entries were made purely to meet EBITDA and included both revenue generating and cost cutting entries designed to impact positively on EBITDA.

222. According to CW-2, Sharad Dubey "made up numbers out of thin air" on the call for each staff accountant to insert into their cash flow projections to be included in the financial statements for the month of June 2022. CW-2 recalled that Dubey would continuously provide new numbers, and the consolidated finance reports would be refreshed hour after hour (first at 6 pm, then at 8 pm, then at 10 pm, etc.) until "good EBITDA numbers were reached."

223. CW-2 described himself as being shocked by Dubey's directive, and further describing the situation as something he could not believe he was hearing, advising that it "clearly violated GAAP." CW-2 reiterated that Dubey directed the staff accountants to insert made up numbers on every monthly call CW-2 attended throughout his tenure for Dubey's stated purpose of making EBITDA, adding that CW-2 attended every monthly call throughout his tenure of June 2022 to November 2022. CW-2 recalled that whenever staff accountants questioned Dubey's requested journal entries, Sharad Dubey told them just to do it.

224. Based on his experience at Catalent, CW-2 believes Dubey's practice of directing staff accountants to insert false numbers into the financial statements had been occurring prior to the start of CW-2's tenure, recalling how "nobody seemed surprised" by Dubey's directive that was given on the first monthly call that CW-2 attended in June 2022. CW-2 advised that another indication to him that this was occurring before his tenure began was that he recalled colleagues telling him that Dubey also directed them on what entries to make when Ernst & Young requested documentation whenever that firm conducted an audit.

225. CW-2 stated that he could not personally make the journal entries and recalled that it was the accountants like Ben Heile (Senior Revenue Accountant) and other CPAs who made all the journal entries that Sharad Dubey directed to be made. CW-2 advised that this occurred on each of the monthly closing calls that happened during his tenure, adding that he sometimes stayed for the entire monthly call especially at the beginning of his tenure and other times, he left the call when the accounts receivable portion ended.

226. CW-2 described Dubey as having a "tyrant style," and that CW-2 acted as a buffer between his team and Dubey as it related to the inappropriate directives. According to CW-2, Dubey was under intense pressure to "deliver to corporate," and as a result, Dubey yelled at and acted dismissively towards those beneath him in the reporting structure when they questioned his directives to insert fabricated numbers into financial statements, which were then sent to corporate headquarters through OneStream.

227. According to CW-2, Harmans' accounting was not accurate given the underlying issues with lack of internal controls. CW-2 recalled Sharad Dubey telling him that he (Dubey) had been hired to get Catalent's accounting in shape. CW-2 described Dubey as seemingly having the ability to make decisions on cutting deals with customers and recalled Dubey's

supervisor Jesse Boyd (Vice President Finance, Cell, Gene and Protein Therapies), as giving him free reign. CW-2 stated that Boyd reported to CFO Tom Castellano.

228. According to CW-2, Dubey needed him to show $400 million of cash flow over a six-month projected budget for an upcoming Board of Directors meeting that was to be held at Harmans' in or around September 2022. According to CW-2, Harmans' aging accounts receivables at that time were equal to approximately $50 million, and in response Dubey directed him to then go back and include all WIP as well as the bad debt stuck in legal, which were invoices being disputed by customers. CW-2 advised Dubey that bad debt cannot be included in cash flow projections under the GAAP, but that even with both the bad debt and WIP included, CW-2's revised six-month projection was still only equal to approximately $100 to $120 million. CW-2 recalled that Dubey responded that he could not go back to corporate headquarters with that number and hung the phone up on CW-2 in frustration.

229. CW-2 explained that following the Board meeting at Harmans in or around September 2022, he asked Jesse Boyd, Vice President, Finance, Cell, Gene, and Protein Therapies, who was at Harmans for the Board meeting, how the Board of Directors reacted to Harmans' financial statements, and CW-2 stated that Boyd told him that "The meeting went well." CW-2 stated he could not understand how the meeting could have gone well when 60% of Harmans' accounts receivables were in "bad debt" and Catalent was "not driving any business or cash flow."

(4) Bad Debt Routinely Understated

230. CW-2 stated that "Standard accounting did not occur at Catalent," adding that the Company was not reserving against old and uncollectible invoices. CW-2 advised that Catalent was supposed to be reserving as bad debt any debt/disputed charge older than 120 days (four months). According to CW-2, disputed customer invoices were sitting in legal and were not

being reserved for in bad debt because that would not look good for Catalent and would have raised concerns from investors. CW-2 added that Catalent routinely understated bad debt and did not book disputed customer invoices as bad debt as they should have, adding that bad debt should be reserved for, but that would have looked bad on Catalent's books.

231. According to CW-2, 60% of Catalent's accounts receivables were sitting in legal because customers were disputing the invoices they received. CW-2 explained that Catalent had "major cash flow problems" because "60% of all accounts receivables were sitting in legal." CW-2 explained that when customers dispute charges or invoices submitted for payment, that the expected revenue from those requests for payment are considered to be "sitting in legal" and cannot be used in revenue projections, according to GAAP rules, because there is no expected time frame for a resolution. CW-2 advised that accounts receivable sitting in legal could not be pulled into a cash flow projection.

232. CW-2 advised that he was aware of the amount of bad debt sitting in legal because he ran monthly accounts receivable aging reports that detailed why the receivables were in legal, which he in turn entered into OneStream on a monthly basis for corporate review. CW-2's access on OneStream was limited to accounts receivable and A/R aging profiles for all of Catalent's global customers.

233. CW-2 confirmed that Dubey also told the accountants exactly what to input for the bad debt general ledger entries. According to CW-2, Dubey was pulling numbers "out of his ass" and that the accountants were forced to make entries without any justification. CW-2 added that this violated GAAP because you need to show a paper trail to justify the numbers being entered on general ledger entries.

234. CW-2 advised that Catalent's Accounts Receivable personnel had no voice in what was counted in bad debt, adding that Sharad Dubey directed the accountants what to put into the bad debt journal entries. CW-2 described Catalent's Accounts Receivable and Accounts Payable personnel as having "no power to do their job," and reiterated that Accounts Receivable had "no voice" on bad debt entries.

235. CW-2 recalled that at the time his tenure ended in November 2022, "aging" accounts receivables (not tied up in legal disputes) was $140 or $150 million, adding that a Company with Catalent's value should have $500 or $600 million in aging accounts receivable.

(5) Accounts Payable Understated

236. CW-2 confirmed that Harmans often utilized temporary employees from vendor companies to address operational issues at Harmans. CW-2 explained that Sharad Dubey had a close relationship with Practus, the consulting company CW-2 worked for, and that Dubey would frequently hire Practus employees to conduct "discrete" projects for Catalent's Harmans' facility.

237. CW-2 described Harmans' Accounts Payable department as having a "major log jam" with vendor invoices. CW-2 advised that this was because purchase orders were not being issued in a timely manner which led to delayed payment on vendor invoices. According to CW-2, as a result, vendors were putting Catalent on credit hold and sometimes requiring prepayment. According to CW-2, Catalent's accruals were not done correctly from "an SOP standpoint," adding that he had the sense that Catalent did not have an idea what the actual accruals were. According to CW-2, this caused a "major backlog" because accruals "were not being done correctly or appropriately." CW-2 added that the vendor invoices "not coming in" and inaccurate accruals also contributed to Harmans' inaccurate EBITDA and an overall inaccurate P&L statement.

238. CW-1 explained that when Harmans brought in temporary employees for Project Phoenix, it was expensive and that Sharad Dubey "took an aggressive position" on accounting for vendors such as those by amortizing their expenses over an unusually long period of time, rather than timely recording the expenses. CW-1 added that this was one of Dubey's many accounting tricks to make Catalent's balance sheet appear better than it was.

(6) Internal Audit at Harmans/BWI Facility in Mid-2022 Reveals Pervasive Weaknesses in Internal Controls

239. CW-1 recalled Catalent's small internal audit team of four or five personnel, conducted an internal audit at Harmans prior to him joining the company in August 2022. CW-1 recalled that the internal audit was conducted on a "nine-month look back" basis at the Harmans' facility only. According to CW-1, the internal audit team presented their "brutal findings on control issues to the C-suite" at a Board of Directors' meeting in approximately September 2022. CW-1 advised that he, Jesse Boyd, Sharad Dubey and the "entire finance department" at Harmans received the final internal audit report, as did: (i) Chief Accounting Officer Karen Santiago; (ii) Catalent's Audit Committee; (iii) CFO Tom Castellano; and (iv) Ricky Hopson because the audit touched on every department at Harmans.

240. CW-1 stated that the internal audit report highlighted that: (i) every level of the finance department at Harmans lacked necessary experience; and (ii) folks at Harmans did not know what other people were doing. CW-1 also recalled that the report included recommendations that he and Ben Heile had to address to "get things fixed."

241. CW-1 recalled changes in accounting personnel in late 2022 after the Company released its 10-Q in November 2022 disclosing that Catalent's earnings had fallen to zero. According to CW-1, Karen Santiago was hired as Catalent's new Chief Accounting Officer in

September 2022, and that as soon as her tenure began, she announced that she was bringing in her own accounting team to get to the bottom of Catalent's accounting issues.

(c) Vaccine Demand Slows and Is Not Replaced with High Demand for Non-Vaccine Products

242. Former Catalent employees confirm that it was "very evident" and "everyone knew" that there was going to be a "lull" after COVID and there was the "longstanding idea that we'd [Catalent] have to brace for that [the slowdown in demand for COVID vaccines]." Indeed, by no later than calendar Q2 2022, significant production capacity was opening up at the Bloomington facility as at least one vaccine customer was leaving Catalent and Catalent could not easily replace the business. Because of the lack of new non-vaccine business in the pipeline, there was a "massive exodus" of Catalent Project Managers in the Fall 2022 because the PMs realized that there was no money coming in with the vaccine business slowing down a lot and with "no [other] business in the pipeline."

(1) The Individual Defendants Participate in Periodic Meetings Regarding Changing Demand Landscape

243. CW-3 advised that he "had direct interaction" with senior management on the AstraZeneca COVID vaccine because of its importance to Catalent. CW-3 recalled that he participated in weekly and bi-weekly calls, referred to internally as "Portfolio Reviews," on the COVID vaccines that Catalent was manufacturing – including AstraZeneca, Moderna and Johnson & Johnson ("J&J") and that all the assets that were currently being used for COVID reported up through this mechanism. According to CW-3, these Portfolio Review calls also included: (i) then CEO John Chiminski; (ii) then CFO Thomas Castellano; (iii) then COO Alessandro Maselli; (iii) Kay Schmidt (Senior Vice President, Enterprise Functions, Chief of Staff); (iv) Karen Flynn (President, Biologics and Chief Commercial Officer); (v) Mike Riley (President – Biologics North America); (vi) Allyson Norrick (CW-3 counterpart from

Bloomington); (vii) current Head of Business, Buildings C & D, (viii) Amanda Henry (former Principal Project Manager who was the COVID vaccine lead at Bloomington), (ix) Roy Satchell, former Head of Global Strategic PMO (Chief of Staff Kay Schmidt's "right hand man" and essentially "everyone's right hand" who had become a "fixture" at Catalent based on his long tenure at the Company); and (x) accounting personnel. According to CW-3, he was responsible for presenting information and answering questions regarding the Harmans/BWI site on the Portfolio Reviews.

244. CW-3 said that initially the Portfolio Review meetings were weekly, and then became bi-weekly, and ultimately monthly as vaccine production became further under control. CW-3 explained that the "Portfolio Reviews" occurred over either MS Teams or Zoom and were set up by Catalent leadership. According to CW-3, anyone with a high-profile project provided a "dashboard update" including slides that were combined by the coordinator who assembled the final slide deck for discussion. CW-3 couldn't recall if there were minutes kept of the meetings. According to CW-3, the Portfolio Review calls also were attended by his counterpart from the Bloomington facility producing the Moderna vaccine, and his counterpart running the filling of AstraZeneca vaccines in Italy. CW-3 said that during the Portfolio Review calls, the participants would report on the status of their programs, including discussions related to product demand and manufacturing capacity.

(2) <u>High Demand for Non-Vaccine Products Does Not Materialize During Class Period</u>

245. CW-9 stated that it was "very evident" and "everyone knew" that there was going to be a "lull" after COVID and there was the "longstanding idea that we'd [Catalent] have to brace for that [the slowdown in demand for COVID vaccines]."

246. CW-10 recalled that in calendar Q2 2022, he participated in a call with the entire sales team which was led by Hamid Farzad. CW-10 advised that Farzad instructed the Sales Team that capacity had opened up at Bloomington and needed to be filled. CW-10 explained that one of the companies that Catalent was producing COVID vaccines for was "walking away," opening up one of the high-speed lines at the facility. According to CW-10, Farzad said that the Company was getting "signals" that this line was going to be opening up and there was an urgency to backfill it with other clients. CW-10 explained that few other products could run on the high-speed lines at Bloomington and that it would take three months minimum and more likely six months, to transition a new product onto that line. CW-10 confirmed that it would have taken "perfect timing" to find a client to fill that capacity due to the need for a client with a large vial program. CW-10 described it as "like hunting a whale" to find one of those clients. CW-10 recalled that some programs were added to the line, but that it could not be completely backfilled.

247. CW-2 recounted there was a "massive exodus" of Catalent's Project Managers (PMs) in the Fall 2022 because the PMs realized that there was no money coming in with the COVID vaccine business slowing down a lot and with "no [other] business in the pipeline."

(d) Financial Information from Catalent's Production Facilities Shared on OneStream Platform

248. CW-8 explained how revenue and costs were reported from each of Catalent's locations to the Company's headquarters in Somerset, New Jersey. CW-8 advised that each Catalent location entered their top-side adjusted numbers (revenue, revenue projections, and costs) into Catalent's revenue database or software program that was the Company's "ERP ledger," (which communicated with Hyperion) and then each group Financial Vice President

would then review the numbers in Hyperion before making top-side adjustments in the ERP ledger.

249. CW-8 explained that regardless of what revenue numbers and projections were provided by each location, the "top side" numbers were "controlled" by the Vice Presidents of Finance for each group and Ricky Hopson (Catalent's Corporate Controller) before the numbers became final in Hyperion. CW-8 recalled that Catalent was planning to transition from Hyperion to a new system called OneStream which was scheduled to be implemented around June 2022. CW-8 summarized the process as follows: (i) each location submitted their projections; (ii) Somerset consolidated (iii) Financial VPs of each financial group makes a top-side adjustment; (iv) Corporate Controller Ricky Hopson, who was "in charge of consolidations" makes additional topside adjustments; and (v) CFO Tom Castellano then received the projections. CW-8 added that it was the top side numbers that the Catalent tax department derived its tax projections from. According to CW-8, he became familiar with this process over the course of his lengthy tenure at the Company (March 2009 through November 2021).

250. CW-8 confirmed that revenue projections were included in the monthly closings through Hyperion. According to CW-8, each location submitted revenue projections monthly. CW-8 recalled that each location provided 4-month projections based on the previous 3-month and 6-month actual activity or revenue achieved. CW-8 explained that Somerset then consolidated and produced its own "top side" number for the full year. According to CW-8, when Somerset received the actual revenues for two months from a location, then they prepared a "2+10" projection – that is a projection for the final ten months in the fiscal year based on the 2-month actual revenues. CW-8 added that the rest of the fiscal year projections follow that same pattern – "3+9," "4+8," etc., adding that a full year projection is updated each month.

251. CW-8 confirmed that the accounting team was meeting periodically during the month to discuss revenue, costs, and projections updates from each location. CW-8 stated that he knew this because the full year projections were being updated regularly in Hyperion based on updated revenue and costs. CW-8 added that in his position he was seeing the updates monthly which is why he knew that the accounting team was meeting periodically to make those updates.

252. According to CW-9, he utilized the Executive Leadership Team ("XLT") Dashboard which monitored PSQDC metrics. CW-9 explained that the acronym stood for "People, Safety, Quality, Delivery, Cost," and provided the following descriptions for each platform the XLT Dashboard was connected to:

- People stood for the Company's Human Resources platform called Workday which, among other data, included "attrition rates" that were monitored.
- Safety stood for the platform where onsite "incident rates" or accident metrics were updated.
- Quality stood for the Company's deviation reporting platform called TrackWise that manufacturing deviation and other KPI information was pulled from.
- Delivery stood for the Company's ERP platform called J.D. Edwards that "transactions for inventory" were pulled from, and that included supply chain updates as well as inventory on the shelves.
- Cost stood for the Company's finance platform called Hyperion, which was then replaced by OneStream, which is the platform that the Company's "P&L" and finance and cost information from each facility was uploaded into.

253. CW-9 confirmed that Site Leadership up through the Executive Team had access to the XLT Dashboard. CW-9 stated that the XLT Dashboard allowed the Vice Presidents,

General Managers, Senior Vice Presidents and other senior executives to all access and see the same data from the dashboard. According to CW-9, site individuals were expected to enter their data at least on a monthly basis for tracking purposes. CW-9 advised that the XLT Dashboard received data from "web forms" that were manually filled out as well as live feeds, both of which flowed into the XLT Dashboard.

254. According to CW-9, each Catalent facility uploaded their various KPIs and details/information into each respective database. CW-9 recounted that then he pulled that data from the dashboard, as well as detailed information that had been uploaded by each facility and compiled that information into PowerPoint presentations that were distributed to and used during Catalent's monthly "Executive Committee" or Executive Leadership Team meetings at the Somerset, New Jersey headquarters. According to CW-9, for each presentation, he extracted the information or details backing up the KPIs that were sent through the various platforms in PSQDC. CW-9 advised that this information included how contaminations and deviations were being addressed and was included in the PowerPoint presentations that he compiled for the monthly Executive Committee Meetings. CW-9 added that the severity of the issue was reflected in how it was color coded, either red, yellow, or green. CW-9 noted that if information was color-coded red in a slide, that it was discussed in greater detail in the meetings. CW-9 advised that he was not the only one preparing slides for the Executive Committee meeting PowerPoint presentations.

255. CW-9 confirmed that the Executive Committee meetings were attended by Catalent's C-suite, Senior Vice Presidents, and Vice Presidents. CW-9 advised that he occasionally participated in these monthly Executive Committee Meetings. CW-9 recalled that these meetings were a "two- or three-day affair," given the number of groups and sites that

participated. CW-9 added that the meetings were conducted with a hybrid approach as a result of the global nature of the Company, with people who lived near Somerset attending in person, and others attending by video call such as Teams or Zoom. According to CW-9, the attendees at the Executive Committee Meetings would do a "deep dive" into that data and information each month. CW-9 referred to the meetings as a mechanism for Catalent's senior leadership to review the Company's operational results monthly. CW-9 explained that each individual business unit presented their individual PSQDC metrics and at times would touch on other areas, such as planned expansions or sharing best practices.

256. CW-9 stated that the dashboard was designed to be easily accessible by the Executive Committee, and he specifically recalled Alessandro Maselli accessing data from the dashboard from his own smartphone. CW-9 advised that the data that Catalent's senior executives could access from the dashboard (through their smartphone or computer) were the numbers, metrics, and KPIs. CW-9 explained that the database was based on Microsoft's Power BI and was accessible by phone or desktop. CW-9 reported that did not witness the other Chief-level officers accessing the dashboard, but confirmed that they, along with the Presidents, Senior Vice Presidents, and Vice Presidents at headquarters, could access the dashboards whenever they wanted to. CW-9 strongly believed that if Maselli was accessing the dashboard, the other Chief-level officers were accessing it as well.

257. CW-9 advised that there was a separate presentation and Executive Committee meeting to review each quarter, referred to as the Quarterly Business Review, or QBR, when it came to reporting to investors. CW-9 explained that both "Op Mechs," or operational mechanisms, and QBRs followed the same type of schedule, but QBRs had a greater level of specificity because they occurred at the end of a quarter. According to CW-9, as a member of the

Enterprise Functions Team, he attended specific portions of these meetings and prepared slides where necessary.

(e) Senior Management, Including the Individual Defendants, Are Made Aware of Quality Control and Inventory Problems at Catalent's Facilities

258. CW-6 confirmed there were weekly videocall meetings on Microsoft TEAMS between each business unit and its counterparts at corporate headquarters in Somerset, New Jersey or other locations that were called "ELT" or Executive Leadership Team meetings. CW-6 described the business unit as the Catalent locations that manufactured the same type products such as the injectable business unit and the softgel business unit as two examples. CW-6 added that the General Managers and Financial Directors from each location in a particular business unit would meet weekly via TEAMS with the Vice President of Operations and Vice President of Finance, for that business unit, who worked at Somerset headquarters.

259. CW-6 confirmed that the respective Vice Presidents located at the Somerset would receive the weekly updates from their counterparts at each of the business unit locations, and then relay those updates to the Senior Vice President of Operations and the Senior Vice President of Finance, both of whom had oversight over the operations and finance, respectively, of every Catalent location. CW-6 understood that the Senior Vice Presidents had to report the updates to Catalent's CFO to make him aware of how revenue was trending.

260. CW-6 recalled there also were regular meetings (via TEAMS) of lower tier managers between each location within each business unit, such as lower tier managers at Bloomington and Brussels having regular meetings because they were both part of the injectables business unit. CW-6 also advised that each location closed their months when they submitted their revenue and cost actuals for that month as well as projections into Hyperion and then headquarters consolidated that information.

261. CW-9 confirmed there were weekly calls between the Vice Presidents of each Business Unit, who worked out of Somerset, and the General Managers and Directors of each Catalent facility. CW-9 recounted that these calls would include the Vice President of Finance and the Vice President of Operations of each Business Unit speaking with the GM, Director of Finance, and Director of Operations from each facility in that respective Business Unit. CW-9 explained that the monthly meetings were led by the Directors of Continuous Improvement for each group.

262. CW-9 advised that Quality had its own calls between the Vice President of Quality (at Somerset) and their respective counterparts at each facility within their Business Unit. CW-9 recalled that the Vice President of Operations for Biologics had his own monthly call with the Biologics Business Unit facilities, which included injectables, and if any issues were "red," that is something that was important or urgent and was discussed. CW-9 explained that issues at times required fundamental changes to how the Company operated and did not have immediate solutions available.

263. CW-9 explained that there also were weekly calls, or "operational mechanisms," that included site leadership, Vice Presidents, and the GM. CW-9 stated that sometimes the various segments had individual site meetings instead of, or in addition to, wider meetings in order to discuss more specific issues. CW-9 added that there were instances where he produced slides for these meetings as well.

264. CW-13 explained that the President of the Bloomington facility would have kept Catalent's CEO current on the deviations and Quality Control issues given: (i) how important the Bloomington facility was because it was producing two COVID vaccines (Moderna and Johnson & Johnson); (ii) the fact that the Federal government was involved with Covid vaccines; (iii) the

public pressure regarding the vaccines; and (iv) the fact that Catalent had invested millions of dollars in both the Bloomington facility and the machinery to produce the vaccines as well increasing its personnel at Bloomington to handle making the vaccines and packaging and shipping them out.

265. CW-1 confirmed that although Sharad Dubey reported to Jesse Boyd, Dubey often interacted directly with CFO Castellano. CW-1 knew this because Dubey would tell him that certain materials CW-1 was preparing were being given directly to the CFO, and that Dubey would say he would "put this on" the CFO's desk. CW-1 explained that this was Dubey's way of telling CW-1 that whatever project or projection CW-1 was giving to Dubey, that he better be ready to stand by it because it was going to Catalent's CFO.

(f) CFO Castellano's Termination and Financial Overhaul Afterwards

266. CW-1 explained that approximately one week after CFO Tom Castellano was fired in April 2023, Karen Santiago (Chief Accounting Officer) announced that she wanted to "get her people down to Baltimore" to get an understanding of Harmans' operations, given the problems Bloomington was experiencing. CW-1 stated that he believed Karen Santiago did this in response to what happened at Bloomington, and to see if the same issues were occurring at Harmans. According to CW-1, Karen Santiago sent a team of four people from PwC (PwC was not Catalent's external auditor) to Harmans where PwC stayed for one week. CW-1 described it as Catalent "opening the books" for PwC. CW-1 described this PWC team as "not junior level people." CW-1 and some of his accounting colleagues, including Ben Heile and a Cost Accountant spent that time with the PwC personnel and answered PwC's questions. CW-1 recalled that the nature of PWC's questions were how Harmans recognized revenue, adding that Ben Heile showed them how the process worked. CW-1 advised that PWC was focused mostly

on revenue recognition and inventory costing because that is where there is the highest risk for companies. CW-1 recalled that PWC also spent a lot of time on Harmans' fixed assets. CW-1 recalled the PwC team found a problem with Harmans' fixed assets (hundreds of millions of dollars of Construction in Process). CW-1 recalled that PwC said Harmans had millions in "Construction in Process" that needed to be written off. CW-1 pointed out that such a write off goes to EBITDA.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

267. Lead Plaintiffs allege that the statements ***identified in bold and italics*** within this section were materially false and misleading because, among other reasons, they omitted to disclose material information of which Defendants were aware or were reckless in not knowing. As alleged herein, such statements artificially inflated or artificially maintained the price of Catalent securities and operated as a fraud or deceit on all persons and entities that purchased or otherwise acquired those securities during the Class Period. Because Defendants chose to speak on the issues described below, and thereby put these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts and information regarding these issues. As described below, Defendants created an impression of a state of affairs at Catalent that differed in a material way from the one that actually existed.

1. August 30, 2021: 2021 Financial Results

268. On August 30, 2021, the first day of the Class Period, Catalent issued a press release announcing the Company's 2021 financial results. The press release reported net revenue of $1.19 billion, up from the $947 million reported for the fourth quarter of fiscal 2020. Net revenue from the Biologics segment was $603 million for the fourth quarter of fiscal 2021, an increase of 69% compared to net revenue from the Biologics segment in the fourth quarter of

fiscal 2020. That same day, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss the Company's financial results for the year ended June 30, 2021.

269. On August 30, 2021, the Company filed with the SEC its annual report for its fiscal year that ended on June 30, 2021 (the "2021 10-K"), signed by Defendants Chiminski and Castellano. The 2021 10-K reported that Catalent generated $3.998 billion in net revenue and $585 million in net earnings for the fiscal year ended June 30, 2021. Also on August 30, 2021, the Company issued a press release announcing its results for the fiscal quarter that ended on June 30, 2021. According to the press release, Catalent generated $1.188 billion in net revenue and $182 million in net earnings.

270. The 2021 10-K touted the Company's regulatory compliance and expertise, stating:

> ***Through our*** extensive capabilities, growth-enabling capacity, and ***deep expertise in product development, regulatory compliance***, and clinical trial supply, we can help our customers take products to market faster, including nearly half of new drug products approved by the U.S. Food and Drug Administration (the "FDA") in the last decade. Our development and manufacturing platforms, which include those in our Biologics, Softgel and Oral Technologies, and Oral and Specialty Delivery segments, ***our proven formulation, supply, and regulatory expertise, and our broad and deep development and manufacturing know-how enable our customers to advance and then bring to market more products and better treatments for patients and consumers***.
>
> ***Our commitment to reliably supply our customers' and their patients' needs is the foundation for the value we provide;*** annually, we produce more than 70 billion doses for nearly 7,000 customer products, or approximately 1 in every 24 doses of such products taken each year by patients and consumers around the world.
>
> ***We believe that, through our investments in state-of-the-art facilities and capacity expansion, including investments in facilities focused on new treatment modalities and other attractive market segments, our continuous improvement activities devoted to operational and quality excellence***, the sales of existing and introduction of new customer products,

> and, in some cases, our innovation activities and patents, ***we will continue to attract premium opportunities and realize the growth potential from these areas***.

271. The 2021 10-K also stated that Catalent "provide[s] differentiated development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, and consumer health products at over fifty facilities across four continents ***under rigorous quality and operational standards.***"

272. The 2021 10-K further stated:

> ***We operate our plants in accordance with current good manufacturing practices ("cGMP") or other applicable requirements***, following our own high standards that are consistent with those of many of our large global pharmaceutical and biotechnology customers. We have approximately 1,600 employees around the globe focused on quality and regulatory compliance . . . .

273. Further, the 2021 10-K stated the following with respect to Catalent's manufacturing capabilities:

> ***We operate our manufacturing facilities and development centers in accordance with cGMP or other applicable requirements***. All of these sites are registered where required with the FDA or other applicable regulatory agencies, such as the EMA. In some cases, our sites are registered with multiple regulatory agencies.
>
> ***Our manufacturing operations are focused on employee health and safety, regulatory compliance, operational excellence, continuous improvement, and process standardization across the organization.***

274. The 2021 10-K also touted Catalent's quality assurance for customer products, stating:

> ***We are committed to ensuring and maintaining the highest standard of regulatory compliance while providing high quality products to our customers***, supported by our core value of Patient First. To meet these commitments, we have developed and implemented a Catalent-wide quality management system. We have employees around the globe focusing on quality and regulatory compliance. Our senior management team is actively involved in setting quality policies, standards, and internal position papers as well as managing internal and external quality performance. ***Our quality***

> ***assurance department provides quality leadership and supervises our quality systems programs.*** An internal audit program monitors compliance with applicable regulations, standards, and internal policies. In addition, our facilities are subject to periodic inspection by the FDA, the DEA, and other equivalent local, state, and foreign regulatory authorities as well as our customers. All FDA, DEA, and other regulatory inspectional observations have been resolved or are on track to be completed at the prescribed timeframe provided in commitments to the applicable agency in all material respects. ***We believe that our operations are in compliance in all material respects with the regulations under which our facilities are governed.***

275. Defendants' Quality Control Statements at ¶¶270-74 were materially false and misleading when made in that they failed to disclose the following adverse facts, which were known to or recklessly disregarded by Defendants: Defendants disregarded regulatory rules and industry standards at key manufacturing facilities located in Bloomington, Brussels, and Harmans/BWI, which received FDA Form 483s throughout the Class Period) in order to rapidly produce excess inventory that was used to pad the Company's financial results through improper revenue recognition in violation of U.S. GAAP. Defendants' disregard of quality assurance at Catalent's key production facilities caused production delays, customer cancellations, a reduction in customer spending, and reputational harm to Catalent.

276. Additionally, information from former Catalent employees and contractors confirm that Defendants' Quality Control Statements at ¶¶270-74 were materially false and misleading. These witnesses confirm, among other things: (i) severe quality control and quality assurance issues at the Bloomington, Brussels, and Harmans/BWI facilities that resulted in repeated regulatory FDA violations, huge backlogs of unresolved SOP deviations and management overriding procedures designed to correct those SOP deviations (¶¶131-32; 135-38; 142-43; 157; 159; 167); (ii) routinely unsterile and contaminated conditions at facilities manufacturing pharmaceuticals for customers (¶136); (iii) a constant push by Catalent's senior management to keep manufacturing product despite "major quality issues" in order "to meet

revenue deadlines" (¶168); (iv) consistent complaints by large customers including Sarepta and AveXis for Catalent to stop producing their products so quickly and instead focus on improving the quality of the products (¶169); (v) tens of millions of dollars of product not released due to a serious backlog in correcting deviations at just one facility (¶145); and (vi) disputes with customers and the exodus of customers because of issues around billing for ruined batches discarded due to quality issues (¶214).

277. The Management's Discussion and Analysis ("MD&A") section of the 2021 10-K stated the following with respect to Catalent's in internal controls over financial reporting:

> **Management's Annual Report on Internal Control Over Financial Reporting**
>
> Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. ***Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. GAAP.***
>
> ***Our internal control over financial reporting includes those policies and procedures that:***
>
> - ***pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;***
> - ***provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors;*** and
> - ***provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.***
>
> Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because either conditions change or the degree of compliance with our policies and procedures may deteriorate.

> Our management has assessed the effectiveness of our internal control over financial reporting as of June 30, 2021. In making this assessment, management used the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). ***Based on this assessment, our management concluded that our internal control over financial reporting was effective as of June 30, 2021***.

278. Appended as exhibits to the 2021 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Chiminski and Defendant Castellano certified that "[t]he [2021 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and that "[t]he information contained in the [2021 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

279. Defendants' GAAP Compliance Statements at ¶¶277-78 were materially false and misleading when made in that they failed to disclose the following adverse facts, which were known to or recklessly disregarded by Defendants:

(a) Catalent materially overstated its revenue and earnings by improperly recognizing revenue in violation of U.S. GAAP;

(b) Catalent had material weaknesses in its internal control over financial reporting related to revenue recognition, including admittedly poor controls relating to the accounting for contract modifications, including concessions offered to customers;[39]

(c) Catalent materially understated its inventory reserves for excess, unsaleable, and expiring inventory throughout the Class Period in violation of U.S. GAAP by failing to timely account for its significant increases in inventory levels before and during the Class Period, coupled

[39] Restated 2022 10-K, at p. 103.

with substantial changes in customer demand, increasing customer disputes, and unrecorded bad debt levels for raw materials, component inventory, and work in progress. Indeed, Catalent admittedly failed to apply rigor and skepticism in its business processes, such as inventory reserve-setting (*See* §IV(F),"Catalent's False Financials,") and

(d) as a result of the foregoing, Defendants lacked a reasonable basis for their statements about Catalent's financial performance throughout the Class Period.

280. Additionally, information from former Catalent employees and contractors confirm that Defendants' GAAP Compliance Statements at ¶¶277-78 were materially false and misleading. These witnesses confirm, among other things, that:

(a) Although Catalent was a contract development and manufacturing organization (CDMO), during CW-11's tenure (October 2020 through July 2023), the Company was acting as a distribution center for customers by holding their product for long periods of time. CW-11 stated that per the customer contracts, the liability switches to the customer following production, so it was peculiar that customers were having Catalent hold onto product, especially since most products had a shelf-life of 24 to 36 months, and batches were released and still sitting in the freezer for months. CW-11 recalled asking multiple times about this and never receiving a satisfying answer. CW-11 stated that it felt like something "shady" was going on at the Company. ¶146.

(b) At Harmans/BWI, during CW-3's tenure (March 2019 – November 2021), Catalent produced product faster than its customers wanted and frequently against the clients' explicit wishes. CW-3 corroborated that typically batches held for "much longer" than 2.5 months. According to CW-3, the quality teams were unable to keep up with the amount being produced and the freezers were getting backed up. CW-3 said that Catalent needed the cash coming in, so they said were going to make the product. According to CW-3, Catalent leadership instructed the employees to "keep going, keep going," noting that Catalent had to "meet forecasts" and that the "biggest lever" to accelerate revenue recognition was always producing more for its biggest clients, including as AveXis, Sarepta, and AstraZeneca. CW-3 added that this was because Catalent's "bottom line had to be in the black," adding that "June and July are the fiscal year," and that the biggest pushes to make product came in the final fiscal quarter leading up to that time, even when the client said to not produce anymore. CW-3 also explained that there were meetings every month between the Project Management team and finance where that PMs were instructed to "find more revenue," "find the revenue wherever you can" and that the final report went up to leadership including then-CFO Tom Castellano. CW-3 stated that CEO John Chiminski and then-COO Alessandro Maselli would say to him and his colleagues at BWI "what are you doing to meet revenue targets?" as a way to push employees to meet revenue targets. CW-3 said that Chiminski and Maselli also said to do everything you can to recognize

revenue. CW-3 said it was always, "revenue, revenue, revenue." ¶¶207, 209, 211, 213.

(c) According to CW-10, who joined Catalent before the beginning of the Class Period, every time a batch of product was discarded due to quality issues, there were difficult conversations with customers who had been billed for ruined batches. CW-10 confirmed that a number of customers were leaving Catalent because of issues around billing for ruined batches discarded due to quality issues. ¶214.

281. Additionally, as outlined in ¶¶175-76, CW-1 and CW-2 confirm that tracking of inventory at Catalent was done manually (one person filling in Excel spreadsheets on raw materials), in mid-2022 when they joined the Company. *Id*. It is a reasonable assumption that the same inventory tracking system existed in mid-2021 before they joined Catalent. Indeed, Catalent had no reliable method of tracking old, expired, or unsaleable inventory. Further, with respect to non-existent supporting sales documentation and ineffective internal controls, it is clear from the accounts of CW-1 and CW-2 that those conditions existed at the Company long before they arrived. *See, e.g.*, ¶¶174, 176, 182-86, 190-91, 224, 239-40. As it relates to unsupported and made-up journal entries directed by Sharad Dubey, CW-2 explicitly stated that, "Based on his experience at Catalent, CW-2 believes Dubey's practice of directing staff accountants to insert false numbers into the financial statements had been occurring prior to the start of CW-2's tenure, recalling how "nobody seemed surprised" by Dubey's directive that was given on the first monthly call that CW-2 attended in June 2022. ¶224. CW-2 advised that another indication to him that this was occurring before his tenure began was that he recalled colleagues telling him that Dubey also directed them on what entries to make when Ernst &

Young requested documentation whenever that firm conducted an audit." ¶224. The last fiscal year end audit before CW-2 started at Catalent was in summer 2021.

282. As a result of Defendants' misrepresentations and omissions on August 30, 2021, Catalent's stock price was artificially inflated or artificially maintained.

283. Analysts reacted favorably to Catalent's 2021 financial results. On August 30, 2021, analysts at J.P. Morgan published a note, titled, *F4Q21 Recap: Results & FY22 Guide Above Expectations w/ LT Target Raised to Include Bettera Deal; Maintain Overweight*, in which they stated: "[W]e are encouraged by another solid beat, as strong demand in Biologics continues to offset transient headwinds elsewhere in the business" and noted "ample room for upside as vaccines ramp." Similarly, on August 30, 2021, analysts at Stephens published a note, titled, *CTLT 4Q21 Initial View: Beat, Guide Ahead of Consensus, Acquiring Bettera*, and highlighted "a lot of exciting things to unpack, but bottom line a strong quarter and FY22 guide that we think clears what were increasing expectations into the print." The next day, August 31, 2021, Stephens analysts published a second note, titled, *CTLT 4Q21 Wrap: The Next Episode in CTLT's Growth Trajectory*, and declared "FY21 a banner year for the Company featuring 25% organic growth, which highlighted the value of CTLT's offerings."

284. Similarly, analysts at William Blair published a note on August 30, 2021, titled, *Post-Call Model Adjustments; Increasing Estimates Given Stronger Earnings Across All Segments and Bettera Purchase*, and stated that "Catalent reported fiscal fourth-quarter earnings that were very strong once again." The William Blair analysts also proclaimed that "Catalent is becoming the 'poster child' for the trend toward full-service integration in the contract manufacturing industry (CDMO)." Finally, the William Blair analysts praised "[Catalent] management's ability to execute across so many different fronts and believe the growth and

margin profile is structurally improving[,]" and noted the Company's "robust demand backdrop and the stock's relatively attractive valuation."

2. November 2, 2021: Q1 2022 Financial Results

285. On November 2, 2021, Catalent issued a press release announcing the Company's Q1 2022 financial results. The press release reported net revenue of $1.03 billion, up from the $846 million reported for the first quarter of fiscal 2021. Biologics reported net revenue of $546 million, up from $377 million reported for the first quarter of fiscal 2021.

286. That same day, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss the Company's Q1 2022 financial results for its fiscal quarter ended on September 30, 2021 (the "Q1 2022 Earnings Call"). Among others, Defendant Chiminski and Defendant Castellano participated in the Q1 2022 Earnings Call. During the Q1 2022 Earnings Call, Defendant Chiminski addressed the Company's growing inventory levels by claiming that the inventory increases were not only intentional but designed to protect Catalent against supply chain issues:

> [W]e've had to make additional investments from an overall inventory standpoint, which obviously impacts our working capital. ***But they're the right investments, if you will, necessary to ensure that we continue to reliably supply across all fronts from vaccine through the 7,000 other products that we manufacture.***

287. On November 2, 2021, the Company also filed with the SEC its quarterly report for its fiscal quarter that ended on September 30, 2021 (the "Q1 2022 10-Q"). The Q1 2022 10-Q reported that Catalent generated $1.025 billion in net revenue and $93 million in net earnings for the quarter.

288. The Q1 2022 10-Q stated that the consolidated financial statements were prepared in accordance with U.S. GAAP:

> ***The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting***

> ***principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.*** Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. ***In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.***

289. The MD&A section of the Q1 2022 10-Q reaffirmed that Catalent's financial statements were prepared in accordance with U.S. GAAP:

> **Critical Accounting Policies and Estimates**
>
> ***We prepare our financial statements in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Management made certain estimates and assumptions during the preparation of the consolidated financial statements in accordance with U.S. GAAP.***

290. The Q1 2022 10-Q also stated the following regarding Catalent's internal controls:

> **Disclosure Controls and Procedures**
>
> ***We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. . .Based upon that evaluation, our Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of September 30, 2021, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.***

291. Appended as exhibits to the Q1 2022 10-Q were signed certifications pursuant to SOX, wherein Defendant Chiminski and Defendant Castellano certified that "[t]he [Q1 2022 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and

that "[t]he information contained in the [Q1 2022 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

292. Defendants' GAAP Compliance Statements at ¶¶286, 288-91 were materially false and misleading when made for the reasons set forth in ¶¶279-81.

293. The MD&A section within the Q1 2022 10-Q also touted Catalent's regulatory compliance and growth opportunities, stating:

> **The Company**
>
> We provide differentiated development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, and consumer health products at over fifty facilities across four continents ***under rigorous quality and operational standards***. . . . ***Through our*** extensive capabilities, growth-enabling capacity, and ***deep expertise in product development, regulatory compliance***, ***and clinical trial supply, we can help our customers take products to market faster***, including nearly half of new drug products approved by the U.S. Food and Drug Administration (the "FDA") in the last decade. . . . ***Our commitment to reliably supply our customers'*** and their patients' needs is the foundation for the value we provide[.] . . . We believe that through our investments in state-of-the-art facilities and capacity expansion, including investments in facilities focused on new treatment modalities and other attractive market segments, ***our continuous improvement activities devoted to operational and quality excellence***, the sales of existing and introduction of new customer products, and, in some cases, our innovation activities and patents, ***we will continue to attract premium opportunities and realize the growth potential from these areas***.

294. Defendants' Quality Control Statements at ¶293 were materially false and misleading when made for the reasons set forth in ¶¶275-76.

295. Additionally, as detailed in ¶¶63-65, on or about October 26, 2021, the FDA issued a Form 483 to Catalent's Brussels facility stating it had found, among other things, several infractions including faulty air filtration systems, alarming bacterial growth, and subpar equipment maintenance.[40] Due to the severity of the issues identified in the October 2021 Form

[40] Catalent management received the Form 483 within days of its issuance, but it was only made public the week of January 18, 2022.

483, Defendants know or recklessly disregarded that the Brussels facility likely would need to partially or completely shut down operations to remediate the issues identified by the FDA. Further, due to the anticipated remediation and likely shutdown of the Brussels facility for some period of time, Defendants knew or recklessly disregarded that production of its clients' products at the Brussels facility could be interrupted due the period of remediation. Indeed, Catalent customer Novo Nordisk later announced production delays for its Wegovy pens produced at the Brussels facility. According to media reports, Novo Nordisk's Chief Financial Officer Karsten Munk Knudsen was quoted as saying that, "in hindsight, the company may have made a mistake in choosing Catalent and was now tightly overseeing the firm's filling operations of Wegovy in Brussels."[41]

296. As set forth in ¶¶157-58, CW-7 confirmed that Brussels' production on "new fillings," or new orders, "stopped immediately" in November 2021 soon after the Form-483 was issued by the FDA, while orders already in production continued to be manufactured until they were complete. ¶158. CW-7 advised that full production did not fully restart by the time his tenure ended (Summer 2022). *Id*. CW-7 recalled that after being at a full stop on new fillings for the first few months after he started, some production occurred to test for contamination in the hope that contamination issues had been resolved, but it had not been resolved. *Id*. Additionally, according to CW-6, another problem that Catalent experienced was that soon after the Form 483 was issued by the FDA, some large injectable customers said they wanted to leave Catalent, and a U.S. pharmaceutical company actually left Catalent. Other smaller Catalent customers "built their own manufacturing capacity" in response to the shutdown at Brussels. ¶162. Because

[41] Maggie Fick, *Insight: Wegovy weight-loss injection factory plagued by sterile-safety failures* (July 27, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/wegovy-weight-loss-injection-factory-plagued-by-sterile-safety-failures-2023-07-27/.

sterility is key in the pharmaceutical industry, customers are scared off when there are issues with sterility. *Id.*

297. As a result of Defendants' misrepresentations and omissions on November 2, 2021, Catalent's stock price was artificially inflated or artificially maintained.

298. Analysts reacted favorably to Catalent's Q1 2022 results. For example, on November 2, 2021, Morgan Stanley analysts also published a report, titled, *F1Q22 Review: Organic Growth Momentum Alongside Bettera Drive Outlook Higher; Reiterate OW, PT to $160*, and stated that "CTLT's ongoing efforts to expand capacity in the high growth biologics and [Cell & Gene Therapy] niches position the company well to exceed its FY24 targets . . . with the current valuation [] pointing to an attractive entry point into the stock."

299. Similarly, that same day, analysts at UBS published a note, titled, *F1Q'22 Recap: Slight Top-Line Miss W/ Strong EBITDA / EPS Pull Through; Guidance Raised; PT to $155*, and stated: "Net, we continue to see an attractive multi-year growth story driven by a bullish outlook for biologics (increased capacity coming online through F23), leverage levels that allow for potential M&A, and an attractive valuation."

300. Also, on November 2, 2021, analysts at RBC Capital Markets published a note, titled, *Outlook Continues to Improve Across All Segments: Key Insights from F1Q22 Results*, and wrote that "[t]he improving organic growth outlook and investments the company is making in its manufacturing footprint increases our confidence in the achievability of its 28%+ EBITDA margin target by FY24. PT to $155 (from $145)." In their note, the RBC Capital Markets analysts highlighted that "[Catalent's] ramping biologics investments not only steepen its LT revenue growth outlook, but lengthen the runway for ongoing EBITDA margin expansion."

3. February 1, 2022: Q2 2022 Financial Results

301. On February 1, 2022, before the market opened, Catalent commenced an earnings call with investors and analysts to discuss the financial results for its fiscal quarter that ended on March 31, 2022 (the "Q2 2022 Earnings Call"). Among others, Defendants Maselli, Chiminski and Castellano participated in the Q2 2022 Earnings Call. With respect to the Form 483 received by the Company's Brussels' plant, Defendant Maselli stated: "***[W]e have not experienced any slowdown in our commercial activity or any impact there. And in fact, I can confirm that the demand and the requests for Catalent's services is as high as ever been…"*** Defendant Castellano added: "***We said from the start that this was not a material financial contributor or impact for the company***."

302. Defendants' Quality Control Statements at ¶301 were materially false and misleading when made for the reasons set forth in at ¶¶275-76.

303. During the Q2 2022 Earnings Call, Defendant Chiminski stated: "***[W]e're pleased that our base business, strong growth in product development and robust prescription drug pipeline are more than overcoming some of the headwinds that still exist***."

304. In the Q&A portion of the Q2 2022 Earnings Call, Defendant Maselli also confirmed that some of the Company's vaccine customers would replace vaccine orders with orders for non-vaccine products:

> **Jacob K. Johnson, Stephens Inc., Research Division**
>
> Maybe a question on the drug products side. Obviously, there's been a good amount of benefit from COVID there. I think as Tom mentioned, you have contracts that run into next calendar year. But if and when those dedicated lines free up potentially for other customers, are you already in discussions with, let's call them, non-COVID customers about that capacity?
>
> **Alessandro Maselli, President & COO**

> ***Yes, sure. Absolutely. Look, I wouldn't call them not -- necessarily non-COVID customers. I will call them non-COVID products. So they might be with the same COVID customers. And in fact, I do believe that's the most likely scenario where those partnerships, which, again, have been set in a way that will create partnership and collaboration across the spectrum of the pipeline and not necessarily on these specific products[.] I believe that we're going to continue to give customers the priority to access these lines***.
>
> ***I'm going to continue to underline and underscore that these types of assets, specifically fill and finish lines and the regulators, are in very high demand.*** There is not enough capacity still in the world that would support the current volumes and the future pipeline, more importantly to prefilled syringes***. And so there is demand, there is a line of customer who wanted to access,*** and I do believe we will continue to give a priority to our partners which we have developed such a strategic relationship through the COVID pandemic responses…

305. In his closing remarks of the Q2 2022 Earnings Call, Defendant Chiminski touted the Company's pipeline of products outside of vaccines and the strong demand there:

> ***The pipeline outside of vaccines remains very robust again for drug product,*** and you're going to see a lot more demand specifically in the prefilled syringe, especially with some high-profile blockbuster drugs that are going to these prefilled syringe formats. ***So it's a really an area that has seen robust growth***. I think Catalent has positioned herself very well. Our early acquisition of Cook Pharmica and the follow-on investments that we've made there have been absolutely fantastic, making it one of the most strategic parts of our American assets for the COVID vaccine solution but also for future drug product filling. And then also, our acquiring the asset from DMF, the Anagni facility, which we're continuing on with follow-on investments there, is significant.

306. Defendants' Non-Vaccine Demand Statements at ¶¶303-05 were materially false and misleading when made in that they failed to disclose the following adverse facts, which were known to or recklessly disregarded by Defendants: Catalent was experiencing lower levels of utilization across the Company's Biologics segment, a significant slowdown in customer spending, and broad-based delays in decision making from its large and small European and U.S.-based customers in both its Biologics and Pharma and Consumer Health segments.

307. Additionally, as outlined in ¶245, CW-9 confirmed that it was "very evident" and "everyone knew" that there was going to be a "lull" after COVID and there was the "longstanding idea that we'd [Catalent] have to brace for that [the slowdown in demand for COVID vaccines]."

308. On February 1, 2022, the Company also filed with the SEC its quarterly report for the fiscal quarter that ended on December 31, 2021 (the "Q2 2022 10-Q"). The Q2 2022 10-Q reported that Catalent generated $1.217 billion in net revenue and $97 million in net earnings for that quarter.

309. The Q2 2022 10-Q stated that the financial statements were prepared in accordance with GAAP:

> ***The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X***. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. ***In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included***.

310. The MD&A section of the Q2 2022 10-Q reaffirmed that Catalent's financial statements were prepared in accordance with GAAP:

> **Critical Accounting Policies and Estimates**
>
> ***We prepare our financial statements in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Management made certain estimates and assumptions during the preparation of the consolidated financial statements in accordance with U.S. GAAP***.

311. The Q2 2022 10-Q stated the following regarding Catalent's internal controls:

> **Disclosure Controls and Procedures**

> ***We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures***. Any control or procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Our management, with the participation of our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. ***Based upon that evaluation, our Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of December 31, 2021, our disclosure controls and procedures were effective to accomplish their objections at the reasonable assurance level***.

312. Appended as exhibits to the Q2 2022 10-Q were signed certifications pursuant to SOX, wherein Defendant Chiminski and Defendant Castellano certified that "[t]he [Q2 2022 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and that "[t]he information contained in the [Q2 2022 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

313. Defendants' GAAP Compliance Statements at ¶¶309-12 were materially false and misleading when made for the reasons set forth in at ¶¶279-81.

314. The MD&A section within the Q2 2022 10-Q also touted Catalent's regulatory compliance and growth opportunities, stating:

> **The Company**
>
> We provide differentiated development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, and consumer health products at over fifty facilities across four continents ***under rigorous quality and operational standards . . .***
>
> * * *

> ***We believe that through*** our investments in state-of-the-art facilities and capacity expansion, including investments in facilities focused on new treatment modalities and other attractive market segments, ***our continuous improvement activities devoted to operational and quality excellence***, the sales of existing and introduction of new customer products, and, in some cases, our innovation activities and patents, ***we will continue to attract premium opportunities and realize the growth potential from these areas***.
>
> * * *
>
> Since the start of the COVID-19 pandemic, ***we have taken and continue to take steps to*** protect our employees, ***ensure the integrity and quality of our products and services***, and to maintain business continuity for our customers and their patients who depend on us to manufacture and supply critical products to the market.

315. Defendants' Quality Control Statements at ¶314 were materially false and misleading when made for the reasons set forth in at ¶¶275-276, 295-296. Additionally, former employees confirm that production at the Brussels location was "shut down" for approximately one full quarter, from January to March 2022, and during that time "zero commercial revenue" was generated at the site. Even when production was restarted, it still took a few months of starting and stopping manufacturing as they tested and awaited the results after they produced each batch. If manufacturing at Brussels was shut down for an entire quarter with close to no money being generated, that the CFO and CEO had to be made aware. ¶160. Defendants Chiminski and Maselli were well-informed about the contamination situation at Brussels. ¶165.

316. As a result of Defendants' misrepresentations and omissions on February 1, 2022, Catalent's stock price was artificially inflated and/or artificially maintained. Indeed, Defendants' statements drove the price of Catalent's shares up by approximately 2.5% percent, to close on February 1, 2022, at $106.57 per share.

317. Analysts reacted favorably to Catalent's Q2 2022 results. For example, on February 1, 2022, analysts at Barclays published a noted, entitled *The Beats Keep Coming, Multiple Expansion To Follow*. Regarding the Form 483, the Barclays analysts wrote that

"[m]anagement explained that remedial actions are being taken and they do not expect a material impact to the topline[,]" though "[b]iologic margins are expected to be hit[.]" The Barclays analysts represented that they did "not think the closure to be protracted and believe the overhang to be de-risked." Along similar lines, in a February 1, 2022 note titled *F2Q22 Recap: Revenue, EBITDA, EPS Beat; Guidance Midpoints Raised*, analysts at UBS declared that they "are raising our revenue and EPS estimates and reiterate our Buy rating after CTLT's F2Q22 beat[,]" while stating that "[t]he FDA 483 letter at the Belgium plant appears manageable[.]"

318. Also, on February 1, 2022, analysts at J.P. Morgan published a note, titled *F2Q22 Review: Strong Beat and Raise Again Despite Transient Margin Pressure from 483 Remediation*, and stated that, "F2Q was another strong quarter, and we are encouraged by another guidance raise despite recent noise around the 483 situation." The J.P. Morgan analysts declared that "the acceleration of long-term strategic capacity expansion projects supports our confidence in CTLT's ability to exceed its LT target revenue growth target of +8-10% top-line." Likewise, in a February 1, 2021 report titled *Broad-based Strength More Than Offsetting Transient EU Disruption: Key Insights from FQ22 Results*, analysts at RBC Capital Markets stated, "[W]e are a bit more confident in the sustainability of the company's growth trajectory and encouraged by the resiliency and diversity of its manufacturing footprint, supported by another guidance raise despite the publicized hiccups in Europe."

319. As a result of Defendants' misrepresentations and omissions on February 1, 2022, Catalent's stock price was artificially inflated and/or artificially maintained. Indeed, Defendants' statements drove the price of Catalent's shares up by approximately 2.5% percent, to close on February 1, 2022, at $106.57 per share.

4. May 3, 2022: Q3 2022 Financial Results

320. On May 3, 2022, Catalent issued a press release announcing the Company's Q3 2022 Financial Results. The Company reported revenue for the third quarter of $1.27 billion, increasing 21% compared to the third quarter of fiscal 2021. Commenting on the results, Defendant Chiminski, stated, in relevant part: "Our recent acquisitions in cell therapy in the U.S. and biologics manufacturing in the U.K., as well as the recently approved $350 million investment in Bloomington, Indiana, will provide additional flexible capacity and allow us to deliver an increasing number of products and treatments to patients and consumers worldwide."

321. That same day, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss the financial results for its fiscal quarter that ended on March 31, 2022 (the "Q3 2022 Earnings Call"). Defendants Maselli, Chiminski and Castellano participated in the Q2 2022 Earnings Call. During the Q3 2022 Earnings Call, Defendant Chiminski stated that *"**Our financial results were driven by strong continued growth in our Biologics segment."***

322. Defendant Chiminski also stated:

> Our Biologics segment was again the top contributor to Catalent's financial performance as it experienced organic net revenue growth of 30%, driving an EBITDA increase of $41 million over the third quarter of last year. These strong results … were driven in part by COVID vaccine demand.
>
> ***Demand remained strong in [the Biologics] segment, including a notable increase from several of our large gene therapy customers for viral vector manufacturing***. Given the high utilization of our biologics assets as well as ***projections for continued demand in the years ahead***, we continue to take both organic and inorganic actions to increase our footprint in drug product, drug substance and cell and gene therapy…. ***Viewed holistically, Catalent remains well positioned to continue delivering strong financial performance and growth***.

323. During the Q&A portion of the Q3 2022 Earnings Call, Defendant Castellano stated, in response to a question regarding the decline in Catalent's COVID-19 business, that the Company had "considerably derisked the overall contributions here . . . as part of the fiscal '23

and ***continue to have a line of sight to growth despite that declining demand profile of COVID-related vaccine revenue*** to the 8% to 10% long-term growth target that we have in place for the consolidated company."

324. In response to follow-up from the same analyst, Defendant Maselli stated:

> ***I will state that our relationship with our COVID partners, which has been built through the pandemic, has never been stronger, remains strong and long-lasting,*** despite the fact that we are, as we said, mitigating the risk of COVID revenues and the outlook we provided today, we will always be there for them for whatever needs of their pipeline, COVID- or non-COVID-related, in the next few years.
>
> ***With regards to Biologics specifically, I will tell you that during the pandemic . . . we were very intentional in keep investing and building and accelerating some investments in assets which we could sell in and which we could fill with the programs, which were late stage and non-COVID-related following the different dynamics***.

325. Defendants' Non-Vaccine Demand Statements at ¶¶321-25 were materially false and misleading when made for the reasons set forth in ¶¶306-07.

326. Additionally, as outlined in ¶¶245-46, former Catalent employees confirm that it was "very evident" and "everyone knew" that there was going to be a "lull" after COVID and there was the "longstanding idea that we'd [Catalent] have to brace for that [the slowdown in demand for COVID vaccines]." ¶245. Indeed, CW-10 confirmed, by no later than calendar Q2 2022, significant production capacity was opening up at the Bloomington facility as at least one vaccine customer was leaving Catalent and Catalent could not easily replace the business. ¶246.

327. During the Q3 2022 Earnings Call, Defendants Maselli and Castellano also commented on the regulatory remediation at Catalent's Brussel's facility with Defendant Castellano confirming that, "the Brussels remediation efforts are absolutely the bulk of the margin compression that we saw in comparison to the prior year levels." Notwithstanding,

Defendant Maselli boasted that remediation of the issues identified in the Form 483 was progressing well:

> ***Also in Europe, our drug product facility in Brussels continues to make substantial progress, which has allowed us to begin the restart of manufacturing operations at the site while we continue in parallel to enhance our overall site operations***.
>
> * * *
>
> [***W]e are pleased with the progress and incredible work done by our teams in addressing the 483 as we stated in previous calls***. 483 need CAPAs by definition. And some of those CAPAs require the facility to be paused in terms of manufacturing because they are more invasive and require engineering changes and some others don't.
>
> ***So I would say that our progress in terms of addressing those requiring engineering changes and manufacturing pause have progressed well***. As described in our prepared remarks, we are -- we have restarted manufacturing operations, which is good, especially for patients. But at the other end, we continue to work diligently on all our CAPA plan on that.

328. Defendants' Quality Control Statements at ¶327 were materially false and misleading when made for the reasons set forth in ¶¶130-38, 142-43, 157, 159, 167-69, 214, 275-76, 295-96.

329. Defendant Castellano also addressed the Company's growing inventory levels and falsely represented that the bloated inventory levels were the result of intentional actions:

> Note that our free cash flow has also been negatively impacted the last 2 years by ***our strategic decision at the onset of the pandemic to increase inventory levels, which continue to allow us to have the inputs we need to meet our supply obligations to our patients and customers in a timely manner. When we feel the time is appropriate and are more comfortable with the stabilization of our supply chains, we will begin to reverse course***, which will have a future positive effect on free cash flow.[42]

[42] Defendant Castellano repeated this statement almost verbatim in the Company's Earnings calls on 8/29/22, 11/1/22 and 2/7/23.

330. Further, during the Q&A portion of the Q3 2022 Earnings Call, in response to a question asking if Catalent was seeing its customers destocking due to high inventory levels, Defendant Castellano stated, "***I'm certainly not hearing or seeing that*** . . . ***[N]ot something I'm seeing or hearing across the business***." Responding to the same question, Defendant Maselli stated, *"**[W]e are not seeing that happening across the board. I believe that this is also due to the fact that many areas, at the end, the demand of the market is really strong***. So we are now refocusing on making sure that the market is served with all capacity that we are deploying ***in those high-demand areas***."

331. Defendants' GAAP Compliance Statements at ¶¶329-30 were materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

332. On May 3, 2022, the Company filed with the SEC its quarterly report for its fiscal quarter that ended on March 31, 2022 (the "Q3 2022 10-Q"). The Q3 2022 10-Q reported that Catalent generated $1.273 billion in net revenue and $141 million in net earnings for the three-month period ending March 31, 2022.

333. The Q3 2022 10-Q stated that the financial statements were prepared in accordance with GAAP:

> ***The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X***. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. ***In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included***. Operating results for the nine months ending March 31, 2022 are not necessarily indicative of the results that may be expected for the year ending June 30, 2022. The consolidated balance sheet at June 30, 2021 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. For further information on the

> Company's accounting policies and footnotes, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2021 filed with the Securities and Exchange Commission (the "SEC").

334. The MD&A section of the Q3 2022 10-Q reaffirmed that Catalent's financial statements were prepared in accordance with GAAP:

> **Critical Accounting Policies and Estimates**
>
> ***We prepare our financial statements in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Management made certain estimates and assumptions during the preparation of the consolidated financial statements in accordance with U.S. GAAP.***

335. The Q3 2022 10-Q also stated the following regarding Catalent's internal controls:

> **Disclosure Controls and Procedures**
>
> ***We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding assurance of achieving the desired control objectives***. Our management, with the participation of our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. ***Based upon that evaluation, our Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of May 31, 2022, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.***

336. Appended as exhibits to the Q3 2022 10-Q were signed certifications pursuant to SOX, wherein Defendant Chiminski and Defendant Castellano certified that "[t]he [Q3 2022 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and

that "[t]he information contained in the [Q3 2022 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

337. Defendants' GAAP Compliance Statements at ¶¶333-36 were materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

338. The MD&A section within the Q3 2022 10-Q also touted Catalent's regulatory compliance and growth opportunities, stating:

> The Company
>
> We provide differentiated development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, and consumer health products at over 50 facilities across four continents ***under rigorous quality and operational standards . . .***
>
> * * *
>
> ***We believe that through*** our investments in state-of-the-art facilities and capacity expansion, including investments in facilities focused on new treatment modalities and other attractive market segments, ***our continuous improvement activities devoted to operational and quality excellence***, the sales of existing and introduction of new customer products, and, in some cases, our innovation activities and patents, ***we will continue to attract premium opportunities and realize the growth potential from these areas***.
>
> * * *
>
> Since the start of the COVID-19 pandemic, ***we have taken and continue to take steps to*** protect our employees, ***ensure the integrity and quality of our products and services***, and to maintain business continuity for our customers and their patients who depend on us to manufacture and supply critical products to the market.

339. Defendants' Quality Control Statements at ¶338 were materially false and misleading when made for the reasons set forth in ¶¶130-38, 142-43, 157, 159, 167-69, 214, 275-76, 295-96.

340. Analysts reacted favorably to Catalent's Q2 2022 results. For example, on May 3, 2022, analysts at J.P. Morgan published a note, titled *F3Q22 Review: FY23 Outlook (+8-10%)*

Derisked on Reduced Vaccine Revenue Increased Conviction on LT Upside; Reiterate OW, and wrote that, "in light of investor focus on the post-pandemic outlook, CTLT issued preliminary FY23 guidance, calling for +8-10% organic top-line growth . . . [and] include[d] a *significant reduction* in COVID-19 vaccine contribution." The J.P. Morgan analysts stated that "Catalent's "increased utilization of new capacity coming online across both drug substance (for cell & gene therapy and in Europe) and drug product (prefilled syringes)."

341. Likewise, analysts at Barclays published a note on May 3, 2022, titled *Considerably De-Risked*, and wrote that "[t]he big news on the day was management guiding FY topline growth 8%-10%, while de-risking COVID revs as 'down considerably'" and noted that "[Catalent] management investing $350m to expand capacity in the Bloomington facility" as a reason underlying their belief that Catalent's relationship with Moderna was not over because "[i]f the MRNA contract is dissolving, we would question why management is expanding capacity for additional projects if it could just replace those lost MRNA lines with this new work." UBS analysts also published a positive note on May 3, 2022, titled *F3Q22 Recap: Revenue, EBITDA, EPS Beat; Guidance Midpoints Raised*, and noted that "robust biologic demand (including cell & gene therapy) is being supported by additional capacity coming online" and stated that "we believe that CTLT continues to represent one of the fastest growth stories across our universe."

342. As a result of Defendants' misrepresentations and omissions on May 3, 2022, Catalent's stock price was artificially inflated and/or artificially maintained. Indeed, Defendants' statements drove the price of Catalent's shares up by almost 15% over two trading sessions to close on May 4, 2022, the following trading day, at $104.08 per share.

5. May 11, 2022: Bank of America Healthcare Conference

343. On May 11, 2022, Defendant Castellano presented at the 2022 Bank of America Healthcare Conference ("BofA Conference"). During his presentation, on the heels of Catalent's third quarter earnings announcement on May 3, 2022, Castellano said, "As part of the call last week, we also gave some qualitative commentary around what we expect for fiscal 2023." Castellano continued, "This has been a point of focus and uncertainty for some analysts and investors. So we thought it was important to maybe go out a little earlier than we normally do with some directional color around what the company's expectations are." Castellano added, "[W]e significantly de-risked our COVID-related revenue for fiscal 2023 and ***continue to have line of sight to very strong growth rates[.]***"

344. During the Q&A portion of the BofA Conference, Castellano answered a question regarding the Company 8-10% growth projection, and he said:

> ***In terms of line of sight that we have to being able to backfill COVID, a lot of this comes from the new capacity that we have that's going to be coming online across those fast growing areas that I mentioned; gene therapy, cell therapy, drug product, manufacturing the drug substance as well*** which is an area that, by the way, we're not participating on the DS side of COVID-related revenue that's been a – we've been a beneficiary from a drug product or a sterile fill/finish standpoint when it comes to COVID-related revenue.

345. Later in the Q&A session, Castellano was asked to address a "big concern" that Catalent and its peers "have been adding capacity" in "very tight market." Castellano responded:

> [F]rom a drug product standpoint, I don't spend a lot of time looking at what other players in the space are investing. And that may seem counterintuitive, but the reason for that is ***our decision point on where we're going to deploy capital is not based on just the attractiveness of the market, which is obviously a little bit of a tailwind that is absolutely attractive, but we need to make sure that we have line of sight to filling that capacity with a pipeline that's more within our control***.
>
> ***We're not speculatively adding capacity and then bringing it out online, having it sit idle and then keeping our fingers crossed that we're out [and]***

> ***able to win new business and bring on customers to fill that.*** We need to make sure that we see a pipeline that can support the investments being made across biologics…***But I would say the part of it that makes it more attractive is the fact that we're seeing a maturity of that pipeline.***

346. Defendants' Non-Vaccine Demand Statements at ¶¶343-45 were materially false and misleading when made for the reasons set forth in ¶¶306-07, 326.

347. As a result of Defendant Castellano's misrepresentations and omissions on May 11, 2022, Catalent's stock price was artificially inflated and/or artificially maintained.

6. August 29, 2022: Q4 and 2022 Financial Results

348. On August 29, 2022, Catalent issued a press release announcing the Company's Q4 and full year 2022 Financial Results.

349. That same day, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss the financial results for its fiscal quarter and year ended on June 30, 2022 (the "Q4 2022 Earnings Call"). Among others, Defendants Maselli and Castellano participated in the Q4 2022 Earnings Call. During the Q4 2022 Earnings Call, Defendant Maselli stated. "***One reason why we do like the space of prescription around solid is that you normally have a pretty visibility on the revenues for a fairly good horizon given the prescription nature of the business and the strength of the pipeline***."

350. Further, Defendant Maselli stated that the Company expected its growth to be "***driven by [its] non-COVID business***" and "***overall organic growth expectation is accelerated by the PCH segment as opposed to the Biologics segment."***

351. Defendant Maselli also claimed on the Q4 2022 Earnings Call that Catalent's ***"growth was primarily driven by broad demand for our biologics offering, including the demand for COVID-19-related products, increased demand for our customer prescription products, and a rebound in demand for our consumer health products.***"

352. Throughout the Q4 2022 Earnings Call, Defendants represented that the Company was seeing sustained demand for many of its non-vaccine products which would be making up for the drastic decline in demand for COVID vaccines. For example, during the Q&A portion of the call, in response to a question regarding transitioning vaccine producing assets to non-vaccine products, Defendant Maselli stated:

> ***[T]he transition is mostly seamless**, **meaning that is happening in parallel. One thing that is happening is that mostly the lines in which we are transferring new products, we've been transferring and onboarding new programs are lines which were built in parallel of the COVID line. We always wanted to have the possibility to serve new customers and new programs while still leaving enough capacity to satisfy the COVID vaccine demand, which in many ways is still not totally predictable, although we're now getting to a much better visibility on it. So I would tell you that the transition has been pretty seamless**. You don't have to think about this like stopping vaccine and starting something new, but it is mostly things that are happening on different formats and on different production lines.
>
> With regards of some of the ones that are, in fact, are going to be served out of the -- like of current COVID vaccine lines, which are going to remember -- the entirety of the current vaccine supply is made in vials. For some of these programs, to a large extent, we can onboard them and but it did them on the line while still making the vaccine. ***So it's a kind of phase-in, phase-out type of dynamic as opposed to having a gap in between.***

353. Defendants' Non-Vaccine Demand Statements at ¶¶349-52 were materially false and misleading when made for the reasons set forth in ¶¶306-07, 326.

354. With respect to Catalent's high inventory levels, on Q3 2022 Earnings Call Defendant Castellano stated:

> ***Note that our free cash flow has been negatively impacted the last 2 years by our strategic decision at the onset of the pandemic to increase inventory levels, which continue to allow us to have the inputs we need to meet our supply obligations to our customers and their patients in a timely manner.***
>
> ***When we feel the time is appropriate, and are more comfortable with the stabilization of our supply chain, we will begin to reverse course, which will have a future positive effect on free cash flow***.

355. Defendants' GAAP Compliance Statements at ¶354 was materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

356. As outlined in ¶¶174-241, information from former Catalent employees and contractors confirm that Defendants' GAAP Compliance Statements at ¶354 were materially false and misleading. These witnesses confirm repeated GAAP violations by Catalent during the Class Period, including: (i) journal entries being made without sufficient supporting documentation, without compliance with SOX, and without requisite approval (¶215); (ii) invoices or sales orders issued which violated customer contracts on how and when to bill those customers (¶215); (iii) revenue recognized in violation of ASC 606 which is the governing regulation on recognizing revenue on sales contracts (¶215); (iv) senior finance executives directing staff accountants to make fictitious and unsupported journal entries to make Catalent's financial results appear stronger than they actually were (¶¶221-23); and (v) the understatement of bad debt for uncollectible invoices (¶¶230-35).

357. Former Catalent employees and contractors also confirm (at ¶¶174-83) serious internal control issues at Catalent throughout the Class Period, including with the Company's inventory tracking methodology and inventory documentation (or lack thereof), and a failure to timely write off significant amounts of inventory that was unused, expired, unsaleable, or even unaccounted for. This resulted in Catalent billing large customers, including Sarepta, for materials those customers did not order or need. Indeed, multiple CWs confirm that a majority of the customers at Catalent's Harmans/BWI facility were disputing their raw material invoices. Indeed, customers were "so exasperated with operations" they stated they could not understand how a multi-billion company like Catalent could not account for such things as lifecycle of inventory, sales orders, and purchase orders. Because of these disputes, customer payments were

often delayed and/or needed to be partially written off or reversed through the issuance of a steady stream of credit memos. In approximately September 2022, Catalent's Audit Committee, Defendant Castellano, and others in the corporate suite were presented with the "brutal findings" of an internal audit conducted at Harmans which noted serious control issues requiring remediation.

358. On August 29, 2022, the Company also filed with the SEC its annual report for its fiscal year that ended on June 30, 2022 (the "2022 10-K"), which was signed by Defendants. The 2022 10-K reported that Catalent generated $4.828 billion in net revenue and $519 million in net earnings for the fiscal year ending June 30, 2022. Also on August 29, 2022, the Company announced its fiscal results for its fiscal quarter that ended on June 30, 2022, reporting that Catalent generated $1.313 billion in net revenue and $188 million in net earnings.

359. With respect to Catalent's compliance with GAAP, the 2022 10-K stated:

> These financial statements include all of the Company's subsidiaries, including those operating outside the United States ("U.S.") and are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").
>
> * * *
>
> **Disclosure Controls and Procedures**
>
> ***We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, and our Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures***. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. ***Our management, with the participation of our Chief Executive Officer, and our Senior Vice President and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report. Based upon that***

evaluation, our Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of June 30, 2022, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.

* * *

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. GAAP.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because either conditions change or the degree of compliance with our policies and procedures may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of June 30, 2022. In making this assessment, management used the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on this assessment, our management concluded that our internal control over financial reporting was effective as of June 30, 2022.

> The effectiveness of our internal control over financial reporting as of June 30, 2022 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included in Item 8. Financial Statements and Supplementary Data in this Annual Report.
>
> **Changes in Internal Control over Financial Reporting**
>
> There was no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

360. With respect to the Company's inventory levels, the 2022 10-K stated:

> We also frequently monitor our supply chain to identify risks, delays, and concerns that may affect our ability to deliver our services and products. ***During fiscal 2022, we did not identify any significant risk, delay, or concern that had a substantial effect on such delivery, in part because of our adoption of various procedures to minimize and manage supply disruptions to our ongoing operations, including through business continuity plans and careful attention to inventory levels to assure supply of needed inputs. Our existing procedures, which are consistent with cGMP and other regulatory standards, are intended to assure the integrity of our supply against any contamination***.

361. Appended as exhibits to the 2022 10-K were signed certifications pursuant to SOX, wherein Defendant Maselli and Defendant Castellano certified that "[t]he [2022 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and that "[t]he information contained in the [2022 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company." (*See* Exhibits 31.1 and 31.2).

362. Defendants' GAAP Compliance Statements at ¶¶359-61 was materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

363. With respect to Catalent's compliance with current good manufacturing practices at its manufacturing and other facilities, the 2022 10-K stated:

> ***High Standards of Regulatory Compliance and Operational and Quality Excellence***

> ***We operate our plants in accordance with current good manufacturing practices ("cGMP") or other applicable requirements***, following our own high standards that are consistent with those of many of our large global pharmaceutical and biotechnology customers. We have approximately 1,900 employees around the globe focused on quality and regulatory compliance . . . . ***We believe our quality and regulatory track record to be a favorable competitive differentiator***.
>
> * * *
>
> ***We operate our manufacturing facilities and development centers in accordance with cGMP or other applicable requirements***. All of these sites are registered where required with the FDA or other applicable regulatory agencies, such as the EMA. In some cases, our sites are registered with multiple regulatory agencies.
>
> We have invested $1.81 billion in our manufacturing and development facilities since fiscal 2020 for improvements and expansions, including $660 million in capital expenditures during fiscal 2022. ***We believe that our sites and equipment are in good condition, are well maintained, and are able to operate at or above present levels for the foreseeable future, in all material respects.***
>
> ***Our manufacturing operations are focused on employee health and safety, regulatory compliance, operational excellence, continuous improvement, and process standardization across the organization***…
>
> * * *
>
> ***Failure to comply with existing and future regulatory requirements, including changing regulatory standards or changing interpretations of existing standards, could adversely affect our results of operations and financial condition or result in claims from customers. In addition, changes to our procedures or additional procedures, implemented to comply with public health orders or best practice guidelines as a result of the COVID-19 pandemic, may increase our costs or reduce our productivity and thereby affect our business, financial condition, or results of operations. (emphasis in original).***

364. Defendants' Quality Control Statements at ¶363 were materially false and misleading when made for the reasons set forth in ¶¶130-38, 142-43, 157, 159, 167-69, 214, 275-76, 295-96.

365. As a result of Defendants' misrepresentations and omissions on August 29, 2022, Catalent's stock price was artificially inflated and/or artificially maintained.

7. The Truth Begins to Emerge, But Defendants Continue to Mislead the Market

366. The truth behind Defendants' misrepresentations and omissions emerged through a series of disclosures beginning on September 20, 2022, and ending on May 8, 2023.

(a) <u>September 20, 2022:</u> Washington Post Article (*First Partial Disclosure*)

367. The truth behind Catalent's misrepresentations and omissions about its failure to comply with CGMP began to come to light on September 20, 2022, when the *Washington Post* released an article, after the close of trading, entitled "FDA releasing millions of Moderna boosters as states warn of shortages." According to the article, the FDA had delayed the release of millions of COVID-19 vaccine booster shots filled by Catalent as a result of the poor inspection at Catalent's Bloomington facility in August 2022. FDA officials had raised concerns that vaccines packaged at the Bloomington facility could be contaminated because the facility was not sufficiently sterile.

368. On September 21, 2022, UBS issued an analyst report on Catalent titled, "CTLT Shares Trade Down On FDA Notice Delaying MRNA's Bivalent Booster." The report stated:

> **Bottom Line:** We believe investors remain focused on COVID revenues and the base biologic acceleration (including cell & gene therapy) and the recent FDA notice lowers F23 outlook visibility. CTLT shares traded down ~5% on news the FDA released a Form 483 notice [] resulting in a delay to millions of doses of [Moderna's] new COVID Bivalent Booster. The FDA noted 12 observations in an August inspection of CTLT's Bloomington, IN plant across quality control, record keeping and failure to establish and follow procedures. The inspection appears to have occurred over August 1 to September 1, and we note CTLT reported F4Q22 and gave F23 guidance on August 29. Also, CTLT in January received a Form 483 letter at a Belgium plant related to Novo Nordisk's Wegovy [] resulting in delays to that product's launch. We model Biologic revenues growing 4.7% in F23, below CTLT's 10-15% long-term target, and we see potential downside to

> our estimates due to the visibility on COVID revenues and potential hesitation from future customers due to the notice.
>
> * * *
>
> While CTLT gave no F23 COVID revenue guidance, it indicated it expects COVID volumes to decline ⅔ YY. Recent management commentary suggests this equates to a >50% to ~66% decline in COVID revenues YY. Our model assumes ~ $350M in F23 COVID revenues (~2/3 decline in revenues YY).

369. On this news, Catalent's stock price ***declined by 9.3 percent*** over two trading sessions, falling from $87.15 per share on September 20, 2022, to close at $79.06 per share on September 22, 2022. However, the full extent of Defendants' misrepresentations and omissions was not yet revealed to the market.

(b) November 1, 2022: Q1 2023 Financial Results (*Second Partial Disclosure*)

370. Defendants' misrepresentations were further revealed on November 1, 2022, when Catalent reported disappointing financial results for Q1 2023 ended on September 30, 2022. For the quarter, the Company reported a miss across the board and cut revenue and EBITDA guidance for fiscal 2023 by ~7%.[43] The Company disclosed that its earnings had fallen to zero and lowered its fiscal year 2023 revenue guidance to the range of $4.625 to $4.875 billion from $4.975 billion to $5.225 billion based on, among other things: (i) higher than expected remediation costs at its Brussels' and Bloomington facilities; (ii) "lower consumer discretionary spend" in Catalent's consumer health, vitamins, minerals supplements and nutraceutical business as part of its business; and (iii) and "signs of short-term cash-sensitive decisions by some of our

[43] As previously mentioned, Catalent reorganized its reporting segments effective July 1, 2022, the beginning of fiscal 2023. All segment data reported in the November 1, 2022 press release for periods ending on or before June 30, 2022 "were the result of recasting data previously reported as if the current segments had been in place during those periods." [11/1/22 press release].

customers" in terms of the pace in which they were looking to move certain development programs along. Catalent disclosed that the Q1 2023 miss was due, in part, to a $54M revenue and EBITDA slippage related to the settlement of a take-or-pay contract for the fill/finish of Janssen's viral vector COVID-19 vaccine at Catalent's Bloomington and Anagni sites. The earnings miss and revised guidance revealed that demand for Catalent products and services was much weaker than the Company had been touting.

371. That same day, November 1, 2022, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss its earnings for its fiscal quarter ended on September 30, 2022 (the "Q1 2023 Earnings Call"). Among others, Defendants Maselli and Castellano participated in the Q1 2023 Earnings Call. During the Q1 2023 Earnings Call, Defendant Maselli stated that the Company was anticipating "negative P&L [profit and loss] effects," as Catalent attempted to address the FDA's observations of regulatory violations at its Bloomington and Brussels facilities.

372. During the Q1 2023 Earning Call, Defendant Maselli revealed:

> We are now seeing signs of lower end market demand for nutritional supplements. In addition, we are experiencing delays in the delivery of the new coming manufacturing lines due to shortages of key components at our European suppliers. We have, therefore, adjusted our near-term growth assumptions for our consumer health offerings within our Pharma and Consumer Health segment. While our biopharma and consumer health pipelines remain robust, we are starting to experience signs of cash-sensitive decisions by some of our customers. This is most evident in relationship to inventory levels for finished goods or the prioritization of their candidates as they progress through the pipeline. Our adjusted forecast also reflects in these new trends.

373. On the performance of Biologics, Defendant Castellano stated, in part:

> The segment's EBITDA margin of 21.5% was lower by nearly 900 basis points year-over-year from the 30.4% recorded in the first quarter of fiscal 2022. Year-over-year margin primarily contracted due to the underutilized capacity. Other factors included the remediation activity in Brussels, which

is ongoing as well as the negative carry related to the Princeton and Oxford facilities.

374. On the Company's adjusted financial outlook for 2023, Defendant Castellano reported:

> [O]ur revised expected organic constant currency net revenue growth rate in fiscal '23 is expected to be essentially flat at the midpoint of the guidance range. For full year adjusted EBITDA, we now expect a range of $1.22 billion to $1.30 billion, representing a decline of 5% at the low end of the range and an increase of 1% at the high end of the range compared to fiscal 2022. . . In fiscal 2023, because we just started the implementation of our cost efficiency activities, we now expect adjusted EBITDA to be even more weighted to the back half of the year at approximately 63% to 64%. This also accounts for the much more pronounced year-on-year decline of COVID-related revenue we expect in the second quarter versus the first quarter.
>
> There are a number of factors that continue to negatively impact margins in fiscal 2023 that we reviewed last quarter, but that will be partly offset by our cost saving actions. The factors include headwinds from COVID-related volume declines, inflationary and supply chain pressures, start-up costs related to our acquisitions of Princeton and Oxford, which we are absorbing in our organic assumptions, other pockets of underutilization across the network as we bring on additional capacity and foreign exchange translations as our margin profile is higher outside of the U.S., while the majority of our corporate costs are domestic…

375. During the Q&A, Defendant Maselli briefly addressed Catalent's growing inventory and how the Company was planning on destocking some of that inventory:

> I did tell you that we were in the mode of making sure that we had excess capacity across the board to make sure that there was never the concern of not having enough capacity. I believe given the current macroeconomic environment, we decided that the capacity -- our assessment is the capacity that we have is more than enough for the runway that we have in front of us for the next several quarters, and there will be plenty of time as we rephase the CapEx more in fiscal '24 to be in the same very position to continue to drive long-term growth. So that is really not affecting our long-term outlook here.

376. In response to an analyst question during the Q&A portion of the Q1 2023 Earnings Call, Defendants revealed how the slowdown in customer spending behavior by

Catalent's U.S. and European customers, both in Biologics and the Pharma and Consumer Health (PCH) segments had caused a double-digit impact for the Company's business (and which was attributable to up to 35% of the PCH revenue cut) with Defendant Castellano finally coming clean about the "cash-sensitive decisions that we're seeing from some of our customers."

> We're seeing it across both, I would say, our European and U.S.-based customers. I did say that this is a dynamic that is crossing both our Pharma and Consumer Health and Biologics segments. I would say, on the Pharma and Consumer Health side, it's more related to commercial products and consumer health products. And I think it's really driven by cash decisions. I believe that our customers are making in terms of how they're managing their supply chain. And it's not just tied to smaller customers either…So much more across the board, both large and small customers and also across biologics and the Pharma and Consumer Health.
>
> The only other thing I'll add is related to the examination of the pipeline and progression of their pipeline, some of the slowdown we're seeing there, that's more attributable to the biologics side of the business. But again, I wouldn't say it's only tied to smaller customers. We're seeing some larger customers that may not be in Phase III, but in more earlier Phase I and Phase II programs, just looking to slow play them as they navigate through the macroeconomic environment.
>
> * * *
>
> I would say we've seen a handful of cancellations as we think about the remainder of the fiscal year, but I wouldn't necessarily say it's any different than what we're seeing -- than what we've seen historically. I would say though, the overall progression of not things that are being canceled, but just the pace in which customers are willing to move is where we're seeing the slowdown, right? So this is in programs that are at are being necessarily canceled, but certainly a slowdown and that slowdown both on the Pharma and Consumer Health side as well as the biologics side was what was contemplated in the more conservative view of guidance.

377. During the Q1 2023 Earnings Call, Catalent also acknowledged that its customers were less willing to hold onto product inventory (*i.e.*, product that Catalent could sell to its customers):

> I would say that the cash-sensitive decisions that we're seeing from some of our customers is not only related to biologic-related customers. We're seeing that on the Pharma and Consumer Health side as well, especially as

> it pertains to levels of safety stock inventory that customers are willing to hold at this point in time if they take what we view as a more cash preservation approach to managing their overall supply chain as well as how they're thinking about the prioritization of some of the candidates that they have in their pipeline as well as the timing of the progression of those. So those are, I would say, the larger factors that we continue to see here…
>
> * * *
>
> I would say it's really very widespread. I mean we're seeing it, as I mentioned, not only in the biologics side of the business, but on the Pharma and Consumer Health side. We're seeing it across both commercial products where customers are willing to appear to manage the supply chain to a more conservative level here and not run on the same levels of inventory here as they look to manage working capital… but I would say in that Phase II range where we are seeing maybe some tempered expectations in terms of the pace in which customers are moving through there as they look to potentially manage their care situation.

378. Catalent's revelations about its Q1 2023 results and revised downward guidance for fiscal 2023 came as a shock to the investing public, particularly because they contradicted Catalent's consistent claims of high visibility into customer demand for its products, and therefore a strong ability to predict future revenue. On November 1, 2022, several analysts issued reports commenting on the Company's disclosures.

379. On November 1, 2022, Barclays' analyst Luke Sergott wrote, in an analyst report titled, "Miss/Guide-Down on Macro; Investors Unsure if Conservative Enough; Significant Uncertainty Around the FY Outlook": "It is really hard to gain comfort in a business that suddenly turns negative on the macro in a matter of a few weeks when it is supposed to be long-cycle and have high visibility. Especially when the guide was supposedly set conservatively to start the year. . . Overall, this was a very hard quarter to stomach after recommending the stock for so long."

380. In a November 2, 2022, Morgan Stanley report titled, "F1Q23 Review: Tough Pill to Swallow, But Macro-Driven Reset Provides Opportunistic LT Entry Point," Morgan Stanley analysts noted:

> The weakness was relatively widespread, with mgmt noting customers of all sizes in both Biologics and PCH segments, in both the EU and US, are beginning to feel an impact. They see pockets of weakness in both commercial products as well as clinical development work, with the former bucket seeing customers manage their supply chain conservatively and not operate at elevated levels of finished goods inventory as they manage working capital (with associated destocking expected to play out in a few quarters), while in the latter bucket they see tempered expectations in terms of programs progressing through the pipeline (particularly within Biologics, and in earlier stage development programs which account for ~40% of CTLT's revenue, albeit cancellation rates remain in line vs historical trend).

381. On November 2, 2022, William Blair analyst Max Smock wrote in a report:

> **Biologics.** Segment growth significantly slowed this quarter, with sales down 2% on an organic basis, versus 14% last quarter. As we discussed above, a primary reason for softness this quarter and in our expectations for 2023 growth is pipeline rationalization by some customers, specifically in cell therapy. Management noted that it expects the most prominent reductions in COVID work this year to occur in the second and third quarters, which will likely more than offset a $54 million inflow the company will receive in the second quarter related to a take-or-pay vaccine contract. Further, while management reiterated that its Indiana and Brussels facilities remain operational following several FDA 483 warning letters, we expect a modest impact on segment margins from remediation efforts.

382. On this news, Catalent's stock price ***declined by 31.7 percent*** over two trading sessions, to close at $44.90 per share on November 2, 2022. However, the full extent of Defendants' misrepresentations and omissions was not yet revealed to the market.

383. Despite the revelations made in the Q1 2023 Earnings Call (November 1, 2022), Defendants continued to issue false and misleading statements and omissions in the Q1 2023 press release and during the Q1 2023 Earnings Call related to the Company's revenue and earnings, demand for its products, and quality control at its key facilities. During the Q1 2023 Earnings Call, Defendant Maselli stated: "While we are taking the prudent step of adjusting

guidance as we navigate the exit from the pandemic, ***I want to be clear that our underlying business still displays signed significant areas of strength as some examples. We continue to forecast strong growth for our overall non-COVID business…Our gene therapy business has proven out that the thesis we lay out when we initially acquired the Paragon Bioservices and our overall funnel of new non-COVID opportunities is at a record high***."

384. During the Q&A portion of the Q1 2023 Earnings Call when asked about the "non-COVID based business ramp into the 2023 under new guidance, especially in the biologics sectors" Defendant Castellano stated: "***So again, we're just really looking at things to continue to trend on a non-COVID basis, in line with what we saw in the first quarter in the more conservative view of our guidance that we presented today.***

385. Defendants' Non-Vaccine Demand Statements at ¶¶383-84 were materially false and misleading when made for the reasons set forth in ¶¶246-48, 306-07, 326.

386. On November 1, 2022, the Company filed with the SEC its quarterly report for its fiscal quarter that ended on September 30, 2022 (the "Q1 2022 10-Q"). The Q1 2022 10-Q reported that Catalent generated $1.022 billion in net revenue and zero in net earnings for the three-month period ending December 31, 2022.

387. The Q1 2023 10-Q stated that the financial statements were prepared in accordance with GAAP:

> ***The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X***. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. ***In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included***. Operating results for the three months ending September 30, 2022 are not necessarily indicative of the results that may be expected for the year

ending June 30, 2023. The consolidated balance sheet at June 30, 2022 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. For further information on the Company's accounting policies and footnotes, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2022 filed with the Securities and Exchange Commission (the "SEC").

388. The MD&A section of the Q1 2023 10-Q reaffirmed that Catalent's financial statements were prepared in accordance with GAAP:

Critical Accounting Policies and Estimates

We prepare our financial statements in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Management made certain estimates and assumptions during the preparation of the consolidated financial statements in accordance with U.S. GAAP. These estimates and assumptions affect the reported amount of assets and liabilities and disclosures of contingent assets and liabilities in the consolidated financial statements. These estimates also affect the reported amount of net earnings during the reporting periods. Actual results could differ from those estimates. Because of the size of the financial statement elements to which they relate, some of our accounting policies and estimates have a more significant impact on the consolidated financial statements than others.

389. The Q1 2023 10-Q also stated the following regarding Catalent's internal controls:

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding assurance of achieving the desired control objectives. Our management, with the participation of our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. ***Based upon that evaluation, our Chief Executive Officer and***

> ***our Senior Vice President and Chief Financial Officer concluded that, as of September 30, 2022, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.***

390. Appended as exhibits to the Q1 2023 10-Q were signed certifications pursuant to SOX, wherein Defendant Chiminski and Defendant Castellano certified that "[t]he [Q1 2023 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and that "[t]he information contained in the [Q1 2023 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

391. Defendants' GAAP Compliance Statements at ¶¶387-90 were materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

392. The MD&A section within the Q1 2023 10-Q also touted Catalent's regulatory compliance and growth opportunities, stating:

> **The Company**
>
> We provide differentiated development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, and consumer health products at over fifty facilities across four continents ***under rigorous quality and operational standards . . .***
>
> * * *
>
> ***We believe that through*** our investments in state-of-the-art facilities and capacity expansion, including investments in facilities focused on new treatment modalities and other attractive market segments, ***our continuous improvement activities devoted to operational and quality excellence***, the sales of existing and introduction of new customer products, and, in some cases, our innovation activities and patents, ***we will continue to attract premium opportunities and realize the growth potential from these areas***.

393. Defendants' Quality Control Statements at ¶392 were materially false and misleading when made for the reasons set forth in ¶¶130-70, 275-76, 295-96. In addition, former employees confirm that: (i) Bloomington had closed down part of their facility in response to the

Form 483 issued in September 2022 (¶156); and (ii) customers were leaving Catalent because of the sterility issues identified by the FDA in the Form 483 issued to Bloomington (¶155).

394. According to CW-6, another problem that Catalent experienced was that soon after the Form 483 was issued to the Brussels facility by the FDA, some large customers said they wanted move on from Catalent. CW-6 recalled having these conversations with injectable customers between the issuance of the Form 483 and his leaving Catalent. ¶162. CW-6 advised that a U.S. pharmaceutical company was one customer who left Catalent after CW-6's tenure. CW-6 recalled that other smaller Catalent customers "built their own manufacturing capacity" in response to the shutdown at Brussels. CW-6 explained that sterility is key in the pharmaceutical industry and that customers are scared off when there are issues with sterility. ¶162.

395. As a result of Defendants' misrepresentations and omissions on November 1, 2022, Catalent's stock price was artificially maintained.

(c) November 16, 2022: Stephens Investment Conference (*Third Partial Disclosure*)

396. Defendants' gradual revelation of the truth continued on November 16, 2022, when, at the Stephens Investment Conference, Defendant Castellano disclosed that Catalent's inventory levels in the month of September for Q1 2023 were higher than they had ever been before -- in excess of $700 million and that Catalent was carrying approximately $400 million in excess inventory and was seeing a slowdown in decision making by its customers, further revealing that the Company had misrepresented demand for its products as well as its purported ability to predict future demand. Specifically, Defendant Castellano stated:

> Our inventory levels in the month of November -- in the month of September for the Q1 close were higher than they've ever been before in excess of $700 million. We absolutely need to improve that. Obviously, a lot of this has been driven by supply chain challenges and disruptions.

> We've seen, I think there's parts of this where we'll be able to pull back and are starting to pull back, but there's also, I would say, additional challenges that continue to pop up every day. So we're not quite out of the woods here. So I would say this is an area that I would expect to improve as we get further into the fiscal year. If we're talking about what the historical level of inventory has been, it's -- we're probably about $400 million too high right now.

397. With respect to slowing customer decision making, Defendant Castellano stated:

> We've seen more of an impact on the consumer health side related to consumer spending primarily. We have nutraceuticals. We have consumer health products. We have OTC products. We have vitamins mineral supplements. And we're seeing or hearing that, that product is moving off of shelves at a slower rate here . . . So we're certainly seeing a change in some of the customers needs here related to consumer products.
>
> * * *
>
> On the biologics side of the business, from a macro standpoint, this is where we're seeing I would just say, slower decision-making from customers and we're believing that, that is also driven by the macro environment. We're seeing them really take more of a cash conservation mode. Many of our customers have multiple programs. And obviously, their lead program or lead programs, they're continuing to move at the same pace, but there are several programs within portfolios where we're seeing just a slower decision-making process.
>
> * * *
>
> And a lot of the growth we were expecting to see on the pharma and consumer health side now being impacted by some of these headwinds.
>
> * * *
>
> I would also say, it's a little bit of an inventory impact here on us as well. We can't control how our customers manage their supply chain and what we've learned through this October update here is some of our customers are because products aren't moving off shelves are willing to take a more -- take a different approach to how they manage their supply chain and run on lower levels of safety stock inventory than where they were. So someone like Catalent as a producer, really feels that on both ends, not only our products moving slowly off of store shelves, but you have customers with excess levels of inventory that are going to let some of that bleed in before needing to pick up demand with us.

398. On this news, Catalent's stock price ***declined by 14 percent***, over two trading sessions, to close at $42.07 per share on November 17, 2022.

399. Despite the revelations about the high levels of inventory and slowing demand for gummies and soft gels in the PCH segment, during the Stephens Investment Conference, Defendants Castellano and Maselli continued to issue false and misleading statements and omissions related to the Company's revenue and earnings, demand for its products, and quality control at its key facilities. Indeed, during the conference, Defendant Castellano stated, in part:

> ***And I would just end by saying, again, continue to be extremely well positioned, very confident about our ability to deliver on our 8% to 12% long-term growth outlook based on the assets that we have in place*** and being extremely well positioned to be able to meet the needs of our customers and ultimately the patients.
>
> * * *
>
> ***So fundamentals remain extremely attractive. The market is robust. We've been growing from a non-COVID basis, well in excess of 20% over the last 3 quarters***. We saw it all the way going back to Q3 of the prior fiscal year. And the assumption was that we saw more of a ramp-up in the second half in the original guidance just as a result of the new capacity and investments that we've made, but also the progression and maturity of the pipeline and that progression in maturity is still there, but I would say it's just coming in at a slower clip than what was originally anticipated.
>
> So again, the reason why you may not be hearing this is just more around some of the assumptions we made going into the year. I think that anything that I would say is causing the market to see some sort of overall pullback in growth. ***We're still seeing growth in excess of the long-term outlook for our Biologics business.***

400. During the Q&A portion of Castellano's presentation, Defendant Castellano also made clear that customer slowdowns were not affecting Catalent's drug product side of the business or its gene therapy business: "***This is not a dynamic we're currently seeing on the drug product side of the business where we're working with mostly large-scale commercial programs, I would say, primarily nor our gene therapy business, where we've seen that kind of***

body language from any large players that are in late stage that are looking to move at a very -- - continue to move at a rapid pace."

401. Defendants' Non-Vaccine Demand Statements at ¶¶399-400 were materially false and misleading when made for the reasons set forth in ¶¶245-47, 306-07.

402. As a result of Defendants' misrepresentations and omissions on November 16, 2022, Catalent's stock price was artificially maintained. However, the full extent of Defendants' misrepresentations and omissions was not yet revealed to the market.

(d) <u>December 8, 2022</u>: GlassHouse LLC Issues Damning Research Report on Catalent's Accounting Practices (*Fourth Partial Disclosure*)

403. The truth behind Defendants' repeated misrepresentations was further revealed on December 8, 2022, when GlassHouse LLC, a stock analyst firm, released a report entitled "Accounting Red Flags Plague Catalent, Inc." (the "GlassHouse Report"). The GlassHouse Report opined on two methods used by Defendants to artificially inflate Catalent's reported revenues and misstate its true customer demand.

404. First, the GlassHouse Report provided evidence supporting the claim that Catalent had prematurely recognized more than $568.2 million in revenue during the Class Period in violation of GAAP. According to the GlassHouse Report, this overstated revenue related to products that the Company had manufactured but had not yet billed to its customers. Supporting this estimate, GlassHouse cited management's November 2022 admission that Catalent was holding approximately $400 million of excess inventory on its balance sheet.

405. Second, the GlassHouse Report asserted that Catalent had engaged in channel stuffing — a deceptive practice whereby the Company knowingly sold more products to its direct customers than they could sell through to their respective customers. Through this

practice, Catalent was able to paint a misleading picture of continued revenue growth and sustainable customer demand to its investors.

406. The GlassHouse Report listed numerous red flags that revealed Catalent's deceptive accounting and channel stuffing schemes including, among other things: (i) the rapid increase in Catalent's contract asset and inventory balances; (ii) declining customer deposits; (iii) executive turnover; and (iv) scrutiny of the Company's revenue accounting by regulators.

407. In response to the GlassHouse Report, on December 8, 2022, analysts at Stephens issued a report titled, "First Look: Quick Thoughts on CTLT Short Report," which stated:

> **INVESTMENT CONCLUSION:**
>
> This morning, a short report was released citing "accounting red flags plauge [sic] Catalent." The crux of the argument is CTLT's contract asset/liability balances, which have weighed on cash flow. The Company has called these out and this is not a new concern from investors and something we discussed with the Company at our conference last month. With that said, the piece also highlights low R&D spend (not really applicable to CDMOs) and concerns around CTLT needing to write off inventory (CTLT has "stocked" inventory given an uncertain supply chain, we think this has nothing to do with obsolete inventory). The article also highlights recent management changes and muted FCF, both of which are not new concerns from investors. In short, we will continue to keep an eye on contract asset/liability trends, while the remaining concerns are either invalid or already contemplated in the stock in our view.

408. Following the publication of the GlassHouse Report, Catalent's stock price ***declined 3.6 percent*** to close at $45.54 per share on December 8, 2022.

409. On December 12, 2022, analysts from William Blair met with Defendant Castellano, for a Fireside Chat in connection with William Blair's Healthcare 2023 Focus List. Thereafter, on December 14, 2022, William Blair issued an analyst report on Catalent, stating, in part:

> **Outlook for non-COVID biologics growth remains robust**. While Catalent expects a substantial drop-off in COVID-related work in fiscal 2023 (nearly $750 million headwind off revenue base of $4.828 billion in

> fiscal 2022 per management), total revenue is only expected to decline a few percentages year-over-year. This is due to continued strength in the company's non-COVID base business, which grew 25% on a constant currency basis in the most recent quarter, led by impressive non-COVID biologics revenue growth (we estimate 40%-plus). Within the biologics segment, commentary around Catalent's drug product and gene therapy offerings in particular was positive—in drug product, management noted that Catalent continues to have a leadership position and a robust pipeline that has been accelerated due to tech transfer programs (on track to ramp up in second half of fiscal 2023); in gene therapy, we were encouraged to hear that the majority of revenue is coming from later stage programs, including several programs that are on the verge of commercialization (e.g., Sarepta's SRP-900 program for Duchenne muscular dystrophy). As a result of strength in Catalent's drug product and gene therapy businesses, we believe the company will be able to achieve its updated biologics guidance for fiscal 2023, which we estimate is calling for roughly 30% non-COVID biologics growth year-over-year.

(e) January 9, 2023: JPMorgan Healthcare Conference

410. On January 9, 2023, Defendants Maselli and Castellano presented at the JPMorgan 2023 Healthcare Conference. During the Q&A portion of the presentation, Defendant Castellano spoke about Catalent's non-COVID revenue growth:

> We've seen growth over the last 2 or 3 quarters actually on a non-COVID basis in excess of 20%, which is well above the long-term growth outlook we have from a non-COVID business standpoint of 8% to 12% for a consolidated company, 10% to 15% for our Biologics business and 6% to 10% for our PCH business. ***So we have been seeing consistent growth well in excess of our long-term growth outlook on a non-COVID basis, as I said over the last 3 quarters or so.***

411. During the Q&A portion of the call, Defendant Maselli reiterated that within the Biologics segment, drug products (including pre-fill Syringes), cell therapies and gene therapies were growing much faster than drug products.

> ***And surely, at this point in time, when you look at the relative growth, we see higher growth rates in other areas of biologics in drug products, specifically when it comes to pre-fill syringes and also with regards of gene therapies and cell therapies, plus DNA. All these areas will grow with a growth factor, which is significantly higher in our estimates from drug substance…*** but I don't want to be -- this audience to be misled***. We***

> ***continue to be very excited about drug substance. It's just that the rest is growing even more than that***.

412. Defendants' Non-Vaccine Demand Statements at ¶¶410-411 were materially false and misleading when made for the reasons set forth in ¶¶245-47, 306-07.

(f) February 7, 2023: Q2 2023 Financial Results

413. On February 7, 2023, Catalent issued a press release announcing the Company's financial results for its fiscal quarter ended December 30, 2022 (Q2 2023). The Company reported Q2 2023 net revenue of $1.15 billion, down 6% compared to Q2 2022, Q2 2023 net earnings of $81 million, and Q2 2023 Adjusted EBITDA of $283 million, a decrease of 9% compared to Q2 2022. The Second quarter results compared to the prior year period were negatively impacted by the lower year-on-year demand for COVID-related products. In the press release, Catalent also: (i) reiterated its full-year fiscal 2023 guidance, including net revenue of $4,625 million to $4,875 million and Adjusted EBITDA of $1,220 million to $1,300 million; and (ii) announced that Moderna and Catalent had extended their collaboration to broaden manufacturing partnership across multiple products and formats in North America and Europe.

414. On February 7, 2023, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss the Company's earnings for its fiscal quarter ended December 30, 2022 (the "Q2 2023 Earnings Call"). Among others, Defendants Maselli and Castellano participated in the Q2 2023 Earnings Call. During the Q2 2023 Earnings Call, Defendant Maselli stated, in relevant part:

> ***Our non-COVID business continued to show strength, as we grew organic constant currency net revenue above market at approximately 12%*** despite softness in nutritional supplement demand. ***We brought online new capacity to support areas of market with anticipated high demand, particularly of prefilled syringes, viral vector manufacturing and the Zydis. . .***

415. On the Q2 2023 Earnings Call, Defendant Castellano represented that non-COVID growth in Biologics was expected to return to "***higher levels of growth***" moving forward.

> Total non-COVID revenue growth for the Biologics segment was more than 10%, down from Q1. ***The non-COVID revenue growth rate in Biologics is expected to return to the higher levels of growth we saw in the first quarter driven by increased demand in our gene therapy offering, easier comparisons in Brussels and uptake in demand for several drug product programs***.
>
> * * *
>
> ***…[E]xpecting to see non-COVID growth in the second half more in line with what we saw in the first half, again, in that 20% range, and that will bring our full year non-COVID-related growth to be in the mid-teens***, as I mentioned on the call.

416. During the Q&A portion of the Q2 2023 Earnings Call, Defendant Maselli reiterated that notwithstanding some delays in customer health spending, Catalent expected strong growth in its non-COVID business:

> ***[W]hen you look at the growth in our core business, our non-COVID business, you're still seeing the business growing above market and to be honest, in the mid-teens. And when you look at Biologics specifically, even more exciting than that. So I would tell you, the market that did correct a little bit, but still supporting a very exciting growth perspective for the future.***

417. With respect to Catalent's guidance for Fiscal Year 2023, on the Q2 2023 Earnings Call, Defendant Castellano stated, in part:

> ***[O]ur non-COVID business outlook remains strong with the second half of the year expected to be in line with the growth we saw in the first quarter, which was more than 20% on an organic constant currency basis. For the full year, non-COVID growth is expected to be in the high teens***.

418. Defendants' Non-Vaccine Demand Statements at ¶¶414-17 were materially false and misleading when made for the reasons set forth in ¶¶245-47, 306-07.

419. During the Q&A portion of the Q2 2023 Earnings Call, Defendant Castellano discussed free cash flow and inventory levels. Specifically, Castellano stated, in part:

> ***Free cash flow was again negatively impacted by our strategic decision to maintain increased inventory levels, which we do not expect to change in the short term due to our concerns about the stabilization of the global supply chain and our commitments to our customers to deliver reliable supply.*** Note that approximately 15% of our inventory includes work in progress, with the remainder being raw materials and supplies. As a reminder, we do not include our customers' finished goods in our inventory balance.

420. Defendants' GAAP Compliance Statements, specifically statements about Catalent's inflated inventory levels, at ¶419 were materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

421. On February 7, 2023, the Company filed with the SEC its quarterly report for its fiscal quarter that ended on December 31, 2022 (the "Q2 2023 10-Q"). The Q2 2023 10-Q reported that Catalent generated $1.149 billion in net revenue and $81 million in net earnings for the three-month period ending December 31, 2022.

422. The Q2 2023 10-Q stated that the financial statements were prepared in accordance with GAAP:

> ***The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X***. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. ***In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included***. Operating results for the six months ending December 31, 2022 are not necessarily indicative of the results that may be expected for the year ending June 30, 2023. The consolidated balance sheet at June 30, 2022 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. For further information on the Company's accounting policies and footnotes, refer to the consolidated financial statements and footnotes thereto included in the Company's

Annual Report on Form 10-K for the year ended June 30, 2022 filed with the Securities and Exchange Commission (the "SEC").

423. The MD&A section of the Q2 2023 10-Q reaffirmed that Catalent's financial statements were prepared in accordance with GAAP:

> **Critical Accounting Policies and Estimates**
>
> ***We prepare our financial statements in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Management made certain estimates and assumptions during the preparation of the consolidated financial statements in accordance with U.S. GAAP.*** These estimates and assumptions affect the reported amount of assets and liabilities and disclosures of contingent assets and liabilities in the consolidated financial statements. These estimates also affect the reported amount of net earnings during the reporting periods. Actual results could differ from those estimates. Because of the size of the financial statement elements to which they relate, some of our accounting policies and estimates have a more significant impact on the consolidated financial statements than others.

424. The Q2 2023 10-Q also stated the following regarding Catalent's internal controls:

> **Disclosure Controls and Procedures**
>
> ***We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding assurance of achieving the desired control objectives***. Our management, with the participation of our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. ***Based upon that evaluation, our Chief Executive Officer and our Senior Vice President and Chief Financial Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.***

425. Appended as exhibits to the Q2 2023 10-Q were signed certifications pursuant to SOX, wherein Defendant Chiminski and Defendant Castellano certified that "[t]he [Q2 2023 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]" and that "[t]he information contained in the [Q2 2023 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

426. Defendants' GAAP Compliance Statements at ¶¶422-25 were materially false and misleading when made for the reasons set forth in ¶¶174-241, 279-81.

427. The MD&A section within the Q2 2023 10-Q also touted Catalent's regulatory compliance and growth opportunities, stating:

> **The Company**
>
> We provide differentiated development and manufacturing solutions for drugs, protein-based biologics, cell and gene therapies, and consumer health products at over fifty facilities across four continents ***under rigorous quality and operational standards . . .***
>
> * * *
>
> ***We believe that through*** our investments in state-of-the-art facilities and capacity expansion, including investments in facilities focused on new treatment modalities and other attractive market segments, ***our continuous improvement activities devoted to operational and quality excellence***, the sales of existing and introduction of new customer products, and, in some cases, our innovation activities and patents, ***we will continue to attract premium opportunities and realize the growth potential from these areas***.

428. Defendants' Quality Control Statements at ¶427 were materially false and misleading when made for the reasons set forth in ¶¶130-70, 214, 275-76, 295-96.

429. Analysts reacted favorably to Catalent's Q2 2023 results. On February 7, 2023, analysts at UBS published a note, titled *F2Q23: Biologics Segment Drive A Top Line Beat; FY23 Guidance Maintained*, and wrote:

> CTLT posted a top line beat, driven by the Biologics segment (PCH segment was in-line) with EBITDA and margin also beating and EPS

> missing. Additionally, F23 guidance was reiterated across the board (revenue, adj. EBITDA, adj. NI). F2Q included $54M of adjusted EBITDA related to a COIVD take or pay settlement with JNJ driving the margin improvement vs. F1Q (vs. 24.6% vs. 18.3%). COVID guidance was also raised for the year implying a decline in the non-COVID outlook (CTLT is assuming a ramp in vaccines in F4Q and extended the Moderna agreement).

430. Also, on February 7, 2023, analysts at William Blair published a note, titled *Fiscal Second-Quarter Analysis; Catalent Delivers Better-Than-Expected Results and Reaffirms Fiscal 2023 Guidance*, and wrote:

> We came away from the call feeling incrementally more positive around the outlook for the Biologics segment in particular, and given management's visibility into demand for this part of the business, we continue to believe Catalent's revenue guide is achievable. . .
>
> * * *
>
> While the prioritization of the COVID work led to a slowdown in growth from non-COVID Biologics revenue in the fiscal second quarter, non-COVID Biologics revenue is expected to return to the higher levels the company achieved in its first fiscal quarter (40%-plus year-over-year), driven by increased demand for its gene therapy offerings, easier comparisons in Brussels, and an uptick in demand for several drug product programs. In addition, management emphasized its excellent pipeline visibility in the segment for the remainder of the fiscal year supported by a large backlog of non-COVID work, particularly in gene therapy and for drug product offerings.

431. KeyBanc analysts also published a note on February 7, 2023, titled *CTLT: 2Q23 – Improved Results and Upbeat Cell & Gene Therapy Outlook*, and wrote:

> Catalent showed improving metrics and more granularity around an expected 2H pickup in revenue, profitability, and cash flow with its 2Q23 earnings report and conference call. Beating top line and slightly missing EPS, the Company has slowed its inventory build, cut staffing costs, and expanded its agreements with Sarepta and Moderna for cell and gene therapy (CGT) production and biological production, respectively. Working capital usage of $20M in 2Q23 declined from $261M in 1Q23 and the Company indicated that the CGT outlook continues to gain visibility.

432. As a result of Defendants' misrepresentations and omissions on February 7, 2023, Catalent's stock price was artificially inflated and/or artificially maintained. Indeed, Defendants'

statements drove the price of Catalent's shares up by more than 6.8% percent, to close on February 7, 2023, at $71.58 per share.

(g) April 14, 2023: Business Update *(Fifth Partial Disclosure)*

433. On April 14, 2023, before the market opened, Catalent revealed it expected that productivity issues and higher-than-expected costs at two key manufacturing facilities, (Bloomington and Brussels), would "materially and adversely impact the Company's financial results for the third fiscal quarter and its outlook for the remainder of the 2023 fiscal year." The Company also announced that Catalent had parted ways with CFO Castellano and that Ricky Hopson would assume the role of Interim CFO effective immediately. The Business Update stated, in part:

> In the third fiscal quarter, the Company also experienced productivity challenges and higher-than-expected costs at its drug product and drug substance manufacturing facilities located in Bloomington, Indiana and Brussels, Belgium, where the Company was unable to achieve anticipated productivity levels and associated revenue due in part to the continued need to implement enhancements to its operational and engineering controls following regulatory inspections that occurred earlier in the fiscal year. While these issues are also expected to affect the Company's fiscal fourth quarter to end on June 30, 2023, productivity levels in Bloomington are expected to be restored to previously forecast levels in that quarter. As with BWI, the Company does not expect to make up for the lost production at Bloomington until after the close of the current fiscal year.

434. On this news, Catalent's stock price ***declined 26.8 percent*** to close at $46.32 per share on April 14, 2023.

435. Catalent also announced productivity issues and expected decreased revenue for Q3 2023 from the Company's Harmans/BWI facility purportedly due to the slow ramp-up of the implementation of an enterprise resource planning (ERP) system, but assured the market. "***None of these issues is expected to adversely impact the quality or commercial launch quantities of any product made at BWI in light of, among other things, the level of "bright stock" on hand***."

436. Defendants' Quality Control Statements at ¶435 were materially false and misleading when made for the reasons set forth in ¶¶130-70, 214, 275-76, 295-96.

437. These revelations came as a surprise to the investing public, and analysts responded negatively. On April 14, 2023, analysts at Jefferies published a report, titled *Untimely Problems Produce CTLT Warnings*, and stated that "[t]oday's guidance warning is particularly jarring because it indicates underlying operational issues would limit upside EVEN IF SRP-9001 is approved, at least in the near term []" and wrote "F3Q Not Looking Good…and Neither Is the FY."

438. On April 14, 2023, analysts at Barclays published a note, titled *Negative pre-a on mfg challenges at gene trx site; CFO change*, and deemed Catalent's announcement "surprising . . . given the bullish commentary this March at our conference on the FY guide and how conservative 3Q guidance appeared." The Barclays analysts added, "To us, the biggest red flags are the Brussels and BWI sites having productivity issues," and said, "[w]e understand that going through an ERP upgrade/implementation is akin to a corporate colonoscopy, but we question the timing of the implementation." The Barclays analysts further stated, "[on] the base business going forward and given the issues throughout the year, we would be more comfortable if mgmt. took all guidance off of the table and reset expectations for the next couple of years. There are too many dynamic trends in the market, particularly around COVID vaccine demand and how this continues to roll off, that would make guiding out a year difficult, let alone 3."

439. Also, on April 14, 2023, analysts at Stephens published a report, titled *First Look: Productivity and Costs Expected to Weigh on CTLT FY23 + Interim CFO*, and wrote that the pre-announcement "released a slew of headlines including productivity issues at BWI and cost issues at Brussels/Bloomington" and noted that, in total, the update was "clearly disappointing

and suggests consensus and our estimates need to come down." The Stephens analysts added, "[w]e suspect this news could represent the final capitulation for fundamental longs in the name and CTLT is firmly entrenched in the penalty box."

(h) May 8, 2023: Notification of Late Filing and Announcement of Accounting Adjustments for Bloomington Manufacturing Facility (*Sixth Disclosure*)

440. Then, on May 8, 2023, before the market opened, Defendants shocked investors by disclosing that Catalent would be delaying the release of its third fiscal quarter results until May 15, 2023, and would be filing a Form 12b-25, Notification of Late Filing, with the SEC because, in addition to the productivity and cost issues identified on April 14, 2023, the "Company identified certain potential non-cash adjustments related to its operations in Bloomington, Indiana" and expected to record a goodwill impairment of more than $200 million in the Company's PCH segment primarily related to its October 2021 acquisition of Bettera Wellness.[44]

441. Defendants also disclosed, on May 8, 2023, that the Company had identified significant issues with its forecasts and expected to significantly reduce Catalent's fiscal 2023 net revenue and Adjusted EBITDA guidance by more than $400 million each. Specifically, Catalent announced:

> Last week, in the course of finalizing its financial statements for the third fiscal quarter ended March 31,2023, the Company identified certain potential non-cash adjustments related to its operations in Bloomington, Indiana, and will need more time to review this matter prior to filing its Quarterly Report on Form 10-Q on May 15, 2023.
>
> When combining the operational and productivity issues, the prior forecasting challenges, and, less significantly, the potential non-cash adjustments, the Company expects to significantly reduce both its fiscal

[44] On May 11, 2023, Catalent filed a Form 12b-25, which noted that the Company required even more time to complete its preparation of the Company's financial results for Q3 2023 ended March 31, 2023.

> 2023 net revenue and Adjusted EBITDA guidance by more than $400 million each. In addition, the Company expects that its income statement and balance sheet will reflect a goodwill impairment in our consumer health business of more than $200 million, primarily related to its October 2021 acquisition of Bettera Wellness.

442. On this news, Catalent's stock price ***declined 25.7 percent*** to close at $35.46 per share on May 8, 2023.

443. These revelations came as a shock to the investing public and analysts responded negatively. On May 8, 2023, analysts at Barclays published a note, titled *UPDATE: CTLT cuts >$400m out of revs and EBITDA for FY'23; new EPS date on the 15th; update to our FY'24 EBITDA range*, and wrote that "[t]oday's news that revenues and EBITDA are >$400m lower than their FY'23 targets comes in well below any downside scenarios we worked through with investors[]" and posited that [t]he bigger question remaining is if there is more to come or if this is the final reset that many are looking for." The Barclays analysts concluded their note by stating, "we can only surmise that these new numbers look de-risked and conservative, but on the other hand, we will have to wait to see if another shoe drops."

444. Similarly, on May 8, 2023, analysts at Jefferies published a report, titled *Problems with Bs – Bloomington, Baltimore, Brussels, Bettera*, and stated that the announcement revealed that "the previously disclosed operational challenges . . . seem to require additional spending to correct[]" and "we think the situation has more moving parts than just a revenue reduction." The Jefferies analysts stated, "[o]ur read of Monday's PR is a bigger loss of revenue from the same places . . . mostly, if not all, Biologics units."

445. Also on May 8, 2023, analysts at J.P. Morgan published a report, titled *Part two of the operational challenges; Hopefully the third installment is better…*, and wrote:

> We believe the > $400mn decline in revenue and EBITDA accounts for a number of areas including reduced performance (productivity) obligations[]; lowered revenue recognition due to lowered/incomplete batch

> production[]; ERP challenges [] that may have affecting [sic] ordering, delayed revenue recognition or led to the inability to accurately track milestones; and adjustment for over recognizing these items.
>
> * * *
>
> Credibility continues to deteriorate. This is the company's second release and we assume there will be more details (potentially damaging) that may come out next week. Management will also have to field tougher questions with detailed answers (we provide additional questions below). We realize the challenges associated with acquisitions, integration, ERP implementation, COVID coming on and rolling off, form 483s, etc. However, at this point, management has to clearly communicate with tangibles to help investors fully assess the core earnings power, establish a baseline and gain conviction that their pipeline/business is not impaired.
>
> * * *
>
> We expect the ratings agencies to take action and downgrade CTLT[.]

446. Analysts at BofA Securities published a report on May 8, 2023, titled *Downgrade to Underperform: Steeper cut to '23, even more questions than answers*, and deemed Defendants' announcement "troubling developments" and stated "[w]ith mounting operational and forecasting issues, visibility into forward estimates is severely limited and we see shares likely underperforming until these challenges are resolved and investor confidence is restored." The BofA analysts added, "[g]iven CTLT is on a June FY (and FY23 is almost over), this is a much steeper cut than what had been anticipated, and raises even more questions about the nature of the productivity/operational issues that CTLT is facing." The BofA analysts concluded:

> Mgmt. had indicated in their April 14th release that they expected a relatively quick (three- to six-month) resolution to some of these issues, but we're skeptical given the magnitude and scope of the challenges. We also see potential for longer-term reputational damage. CTLT could see some demand erosion as potential drug sponsor clients opt to work with other contract manufacturers given recent missteps.

VI. SUBSEQUENT EVENTS

447. On May 19, 2023, before the market opened, Defendants issued a press release (the "May 19 Press Release") filed with the SEC on Form 8-K announcing, among other things: (i) a further delay in the filing of the Company's Q3 2022 10-Q; and (ii) that Catalent had received a notice from NYSE that the Company was not in compliance with NYSE's continued listing requirements under the timely filing criteria established in Section 802.01E of the NYSE Listed Company Manual, because Catalent did not timely file its Q3 2023 Form 10-Q with the SEC.

448. That same day, on May 19, 2023, Catalent hosted a conference call with investors and analysts to provide the market with a status update (the "the Status Update Call"). Among others, Defendant Maselli and Ricky Hopson, Interim Chief Financial Officer, participated in the Status Update Call.

449. On the Status Update Call, Catalent announced that it was still working on finalizing its financial results for Q3 2023 (ended March 31, 2023), but that it expected to:

(a) restate its financials for fiscal 2022 ended June 30, 2022, because of the improper recognition of $26 million in Q4 2022 in violation of GAAP;

(b) increase its inventory reserves by approximately $55 million related to unsaleable and expiring inventory of manufacturing components and raw materials at the Bloomington manufacturing facility;

(c) report a goodwill impairment of more than $200 million in the Company's consumer health segment; and

(d) assess the effectiveness of the Company's internal controls over financial reporting and disclosure control and procedures; and

(e) assess the effectiveness of its forecasting methods which Defendants determined lacked sufficient "rigor and skepticism" to take account for "known and previously unforeseen macro and internal operations drivers."

450. Moreover, on the Status Update Call, the Company announced a significantly reduced revenue forecast for fiscal 2023 ended June 30, 2023 (with revenue down by approximately $450 million and EBITDA down by about $510 million at the midpoint) due to: (i) an admittedly botched forecasting system lacking sufficient "rigor"; (ii) price concessions given to certain customers; (iii) lost productivity and lost or seriously delayed revenues that "dropped through to the bottom line;" (iv) higher costs caused by the corrective remediation and other problems at the Bloomington, Brussels, and BWI manufacturing facilities; and (v) wildly unrealistic growth projections for the Pharma and Consumer Health segment which was experiencing "pronounced declines in some existing commercial line value pharmaceutical products[,] delayed launches of some promising new prescription products[,] and lower consumer demand[.]"

451. Specifically, on the Status Update Call, Defendant Maselli stated, in relevant part:

> I'll cut to the chase. This is not at all the call that we expected to [have now], and we are not at all where we expected to be. Our financial performance and operational execution have all fallen significantly short of our expectations and our February forecast, and we accept the responsibility for disappointing you.
>
> * * *
>
> As we indicated in our April 14 and May 8 business updates, a combination of operational and productivity issues, as well as forecasting challenges, have led us to significantly reduce both our fiscal '23 net revenue and adjusted EBITDA guidance. We are now reducing our fiscal '23 net revenue guidance to a range from $4.25 billion to $4.35 billion, and we are reducing our adjusted EBITDA guidance to range from $725 million to $775 million. It is important to note that these ranges reflect that our significant gene therapy product begin to be treated in the third quarter as a commercial product for accounting purposes. And while our evaluation remains

ongoing, we anticipate continuing to record revenue for this product entirely on a percentage of completion basis.

* * *

As we first communicated on April 14, during the third quarter, we began to identify productivity challenges and higher-than-expected costs at our drug product manufacturing facilities located in Bloomington and Brussels. These issues drove our EBITDA reduction in our reduced revised guidance to be greater than our revenue reduction due to the following dynamics.

First, even where revenues were delayed or missed, the majority of the labor and overhead costs remained. Second, our plans to reduce our cost base were delayed in order to implement the corrective and preventative actions following the regulatory inspections earlier in the fiscal year in our Biologics segment. Finally, balance sheet adjustment in inventory reserves for soon-to-expire biomanufacturing components and raw materials procured during the height of the pandemic are adding a larger-than normal onetime impact on our profitability. Our gene therapy manufacturing operations in Maryland also faced unforeseen challenges as we scale up commercial volumes, requiring a new ERP system, and successfully completed 3 regulatory inspections.

* * *

Our focus in our Pharma and Consumer Health segment have also been too optimistic. This is a segment where we expected a strong growth as we started the year, modified our expectations to much more modest growth in November and February, and now tracking to flat organic revenue growth for the full year. The main headwinds here are: More pronounced declines in some existing commercial line value pharmaceutical products; delayed launches of some promising new prescription products; and lower consumer demand, particularly for gummies and higher -- and other high-end nutritional supplements. . .

* * *

To recap, we have reviewed the procedure with which we execute our precise processes to determine how macro events impacted our ability to meet our forecast. After delivering 3 years of exemplary performance, we are bringing back more rigor and skepticism, such as known and previously unforeseen macro and internal operations drivers.

* * *

In all, we expect to record a few accounting adjustments at Bloomington. One example, we expect to increase our inventory reserve by roughly $55 million related to [sustain] the raw materials and component to ensure the

> safety stock to minimize pandemic-related supply chain shortages. We're also expected to correct a $26 million recognition error related to the fourth quarter of fiscal '22. Separately, given our lower growth expectations for our consumer health business, we also expect to report a goodwill impairment in that business in excess of $200 million.

452. With respect to the Company's reduced financial outlook for fiscal 2023, Interim CFO Ricky Hopson noted that Catalent expected 2023 net revenue in the range of $4.25 billion up to $4.35 billion, adjusted EBITDA in a range from $725 million up to $775 million and adjusted net income in a range from $187 million up to $228 million.

453. On June 12, 2023, Defendants issued a press release filed with the SEC on Form 8-K announcing that Catalent had finalized its financial results for Q3 2023 ended March 31, 2023. The Company also announced, consistent with its preannouncements on May 8, 2023, and May 19, 2023, that it would be filing an Amended 2022 10-K to correct for the improper recognition of revenue in Q4 2022 ended June 30, 2022. The press release stated, in relevant part:

> As described in the Amended Fiscal 2022 10-K, in preparing Catalent's consolidated financial statements for the three and nine months ended March 31, 2023, Catalent identified a $26 million error related to the over-recognition of revenue in the consolidated financial statements it issued with respect to its fiscal year ended June 30, 2022. This error resulted from the misapplication of the contract modification guidance to one of the Company's customer arrangements in accordance with U.S. generally accepted accounting principles, particularly ASC 606, Revenue from Contracts with Customers. Catalent assessed the materiality of the error both quantitatively and qualitatively and determined this error to be immaterial to those consolidated financial statements. While the revenue recognition error did not result in a material misstatement of the Company's previously issued consolidated financial statements, the Company nevertheless determined to revise those consolidated financial statements it issued with respect to its fiscal year ended June 30, 2022 to reflect the impact of that error in the appropriate period.

454. The June 12, 2023 press release also informed investors that Catalent's internal controls over financial reporting were not effective as of June 30, 2022:

> Due to the discovery of this error, Catalent also re-evaluated the effectiveness of its internal control over financial reporting ("ICFR") as of June 30, 2022 and identified a material weakness in its ICFR as of that date related to the accounting for modifications of customer agreements at our Bloomington, Indiana facility. For a more detailed description of this material weakness, refer to Part II, Item 9A, "Controls and Procedures" in the Amended Fiscal 2022 10-K. The Amended Fiscal 2022 10-K therefore restates Catalent's assessment of its ICFR and its disclosure controls and procedures to indicate that they were not effective as of June 30, 2022 because of this material weakness. Catalent's independent registered public accounting firm, Ernst & Young LLP, has also restated its opinion on Catalent's ICFR as of June 30, 2022.

455. For Q3 2023, the June 12, 2023 press release disclosed: (i) that net revenue had decreased by 19%, year-over-year, compared to Q3 2022; (ii) that adjusted EBITDA had decreased 69% year-over-year, compared to Q3 2022; and (iii) a net loss of $(227) million, included a goodwill impairment of $210 million in the Company's PCH segment primarily related to its October 2021 acquisition of Bettera Wellness. The Company also disclosed that Q3 2023 net revenue in the Biologics segment had decrease of 32% year-over-year compared to Q3 2022 driven by significantly lower year-on-year COVID demand. In Q3 2023, COVID revenue declined approximately 68% to $120 million. As previously disclosed, the Company also significantly reduced its fiscal 2023 financial guidance.

456. Also on June 12, 2023, before the market opened, Catalent hosted an earnings call with investors and analysts to discuss its earnings for Q3 2023 ended March 31, 2023 (the "Q3 2023 Earnings Call"). Among others, Defendant Maselli and Ricky Hopson (Interim Chief Financial Officer) participated in the Q3 2023 Earnings Call. During the Q3 2023 Earnings Call, Defendant Maselli discussed the Company's restated revenue for Q4 2022, the amended 10-K

for fiscal 2022, and the material weakness in ICFR as of June 30, 2022. Specifically, Defendant Maselli stated:

> As expected, we recorded a few accounting adjustments in Q3 at the Bloomington, the largest of which was raw material write-offs and an increase in our -- to our inventory reserve of roughly $55 million related to certain raw materials and components, procured the safety stock to minimize pandemic-related supply chain shortages. We also corrected a $26 million revenue recognition error related to the fourth quarter of fiscal '22. The error relates to a contract modification involving the Bloomington customer that we fail to reflect as such in the quarter. Separately, given our lower growth expectation for our Consumer Health business, we finalized our -- the accounting for a goodwill impairment of $210 million.
>
> * * *
>
> I will note that due to the discovery of this error, we also reevaluated the effectiveness of our internal control over financial reporting as of the end of fiscal '22 and identified a material weakness in our internal control framework or ICFR as of the date -- of that date related to our failure to detect the Bloomington revenue recognition error. Please refer to the amended 10-K for a more detailed description of this material weakness.
>
> As noted in the amendment, management has restated its assessment to our ICFR and our disclosure controls and procedures to indicate that they were not effective as of June 30, 2022, because of this material weakness. Our independent registered public accounting firm, Ernst & Young, has also restated its opinion on our ICFR as of June 30, 2022. However, Ernst & Young's report on the consolidated financial statements remain unchanged and continues to state that our June 30, 2022 financial statements present fairly in all material respects the financial position of the company at the June 30, 2022 and 2021, and the results of its operation and its cash flow for each of the 3 years in the period ended June 30, 2022 in conformity with GAAP.
>
> * * *
>
> The second half of fiscal '23 also reflects some margin issues in our Biologics segment, particularly with respect to our significant investments in new modalities, including cell therapies and plasmids. We're also taking actions in these areas. For context, we believe all these assets will create a great value for innovator inflations over time. However, our expectation earlier in the year for significantly higher revenues related to these assets in fiscal '23 turned out to be not what we are currently experiencing. As a result, these service offerings currently have a very low level of absorption and utilization and are running below breakeven levels, creating an impact

> of several hundred basis points on the EBITDA margin in our Biologics segment.

457. Interim CFO Hopson added: "The accounting adjustments during the quarter were largely due to the reserves or write-offs of raw materials in Bloomington totaling approximately $55 million that we purchased at our own risk as safety stock during the pandemic. This alone impacted segment margin by more than 1,100 basis points." During the Q&A portion of the earnings call, Interim CFO Hopson stated that Q4 2023 COVID revenue would only be about $40 million.

458. On June 12, 2023, Defendants filed with the SEC Catalent's restated Annual Report for fiscal 2022 ended June 30, 2022 ("Amended 2022 10-K"). With respected to the improperly recognized revenue in Q4 2002, the Amended 2022 10-K stated, in part:

> **REVISIONS OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS**
>
> In preparing the consolidated financial statements for the three and nine months ended March 31, 2023, the Company identified a $26 million error related to the over recognition of revenue in the consolidated financial statements it issued with respect to the fiscal year ended 2022. This error resulted from the misapplication of the contract modification guidance in accordance with ASC 606, Revenue from Contracts with Customers, related to one of the Company's customer arrangements. The Company assessed the materiality of the error both quantitatively and qualitatively and determined this error to be immaterial to the 2022 consolidated financial statements. However, the Company concluded that the effect of correcting the error in the quarter ended March 31, 2023 would materially misstate the Company's unaudited consolidated financial statements for the three and nine months ended March 31, 2023 and, accordingly, determined that it was necessary to revise the consolidated financial statements it previously issued with respect to the fiscal year ended June 30, 2022.

459. With respect to the material weakness in internal controls over financial reporting for fiscal 2022 ended June 30, 2022, and the Company's ineffective disclosures regarding controls and procedures, Defendants reported in their Amended 2022 10-K:

We did not maintain effective controls over the appropriateness of revenue recognition related to modifications of customer agreements at our Bloomington, Indiana facility. Specifically, we did not maintain effective controls to properly identify and assess the accounting treatment of modifications to arrangements that were accounted for under ASC 606, Revenue from Contracts with Customers. The reviewer had insufficient knowledge of the requirements of the ASC 606 revenue recognition accounting model and therefore, the review procedures were not performed with the necessary level of competency to prevent or detect a material misstatement on a timely basis. Furthermore, the compensating control to review the accounting assessments for contract modifications was not sufficiently designed to detect accounting misstatements. As discussed in the Explanatory Note to this Amendment and Note 1 to the Consolidated Financial Statements contained in Part II, Item 8, "Financial Statements and Supplementary Data," these control deficiencies resulted in an immaterial revision to our June 30, 2022, consolidated financial statements to correct an overstatement of revenue of $26 million. While these deficiencies did not result in a material misstatement of our consolidated financial statements, there is a reasonable possibility that these deficiencies could have resulted in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected on a timely basis.

In Management's Annual Report on Internal Control Over Financial Reporting included in the Original Form 10-K, management, including our Chief Executive Officer and our Chief Financial Officer, concluded our internal control over financial reporting was effective as of June 30, 2022. Management subsequently concluded that the material weakness described above existed as of June 30, 2022. As a result, management has concluded that we did not maintain effective internal control over financial reporting as of June 30, 2022 based on the criteria in Internal Control-Integrated Framework (2013 version) issued by COSO. Accordingly, management has restated its report on internal control over financial reporting.

* * *

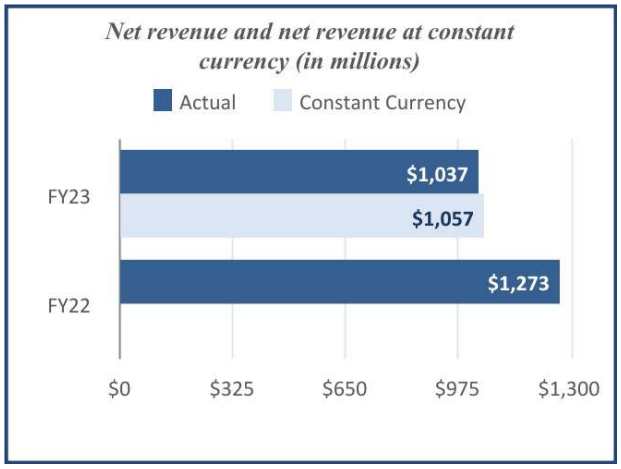
At the time that the Original Form 10-K was filed on August 29, 2022, our management, including our Chief Executive Officer and our Chief Financial Officer, had evaluated the effectiveness of the design and operation of our disclosure controls and procedures and concluded that our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level. Subsequent to this evaluation, our management, including our Chief Executive Officer and current Interim Chief Financial Officer, concluded that our disclosure controls and procedures were not effective as of June 30, 2022, due to the material weakness in internal control over financial reporting described below.

460. Moreover, as part of the "Remediation Plan" for the material weakness in ICFR, the Company was providing, "[a]dditional training for our Executive Leadership Team, and other critical customer-facing personnel, on revenue-recognition principles including contract modifications relating to offered concessions.

461. On June 12, 2023, Defendants filed with the SEC Catalent's quarterly report for its fiscal quarter that ended on March 31, 2023 (the "Q3 2023 10-Q"). The Q3 2023 10-Q also stated in part:

> *Operating Activities*
>
> For the nine months ended March 31, 2023, cash provided by operations was $58 million compared to $370 million in cash provided by operating activities for the nine months ended March 31, 2022. The year-over-year change was primarily due to a decrease in operating earnings, growth in inventory, an increase in interest payments due to higher outstanding debt balances, an unfavorable impact from the collection of trade receivables and an increase in severance payments related to our restructuring plans.

462. The Q3 2023 10-Q made crystal clear how far Catalent's net revenues and gross margins had declined year-over-year (Q3 2023 vs. Q3 2022):



463. The Q3 2023 10-Q also reported a Material Weakness in Internal Control over Financial Reporting as of March 31, 2023 ("2023 Material Weakness"). According to the Q3 2023 10-Q, the material weakness related to "ineffective information technology general controls

(ITGCs") in the areas of user access management . . . that support [the Company's] financial reporting processes" and that "[t]he 2023 Material Weakness will remain in effect."

464. On June 20, 2023, Catalent filed a Form 8-K with the SEC announcing that Matti Masanovich would take the position of CFO effective immediately filling the CFO role vacated by Defendant Castellano on or about April 14, 2023.

465. On August 30, 2023, Catalent revealed that the filing of its Form 10-K for fiscal year 2023 (ended June 30, 2023) would be delayed as the Company "requires additional time to complete its procedures related to management's assessment of the effectiveness of its internal controls over financial reporting as of June 30, 2023 and other closing procedures."

466. Then, on September 15, 2023, Catalent announced it had received notice from the NYSE that it was "not in compliance with the NYSE's continued listing requirements" as the Company had failed to file the 10-K by the extension date of September 13, 2023. This means that Catalent's material weakness in internal controls over financial reporting, which Catalent belatedly reported for the fiscal year ended June 30, 2022, still may be plaguing the Company.

VII. ADDITIONAL SCIENTER ALLEGATIONS

467. As alleged herein, Defendants acted with scienter throughout the Class Period, in that Defendants knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company, or in their own names, were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of or access to information reflecting the true facts regarding Catalent, their control over, or receipt, or

modification of Catalent's allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

468. Defendants knew or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraud described herein could not have been perpetrated throughout the Class Period without the knowledge and complicity, or at least, the reckless disregard, of Catalent personnel at the highest levels of the Company.

469. The Individual Defendants permitted Catalent to release these false and misleading statements and failed to file the necessary corrective disclosures, which artificially inflated or artificially maintained the price of Catalent securities throughout the Class Period.

470. As set forth herein, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Catalent, their control over, receipt of, and/or modification of Catalent's allegedly materially misleading statements and omissions, and/or their positions with the Company that made them privy to confidential information concerning Catalent, participated in the fraudulent scheme alleged herein.

471. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Catalent securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public regarding Catalent's business, operations, and management as well as the intrinsic value of Catalent securities, and caused Lead Plaintiffs and members of the Class to purchase Catalent securities at artificially inflated or artificially maintained prices.

472. The following allegations all support a strong inference of scienter:

(a) Statements by former Catalent employees corroborate that Defendants knew or were reckless regarding the falsity of their statements and omissions during the Class Period at the time such statements were made;

(b) Catalent's improper revenue recognition in Q4 2022 allowed the Company to beat Wall Street consensus estimates when the Company would have missed consensus estimates without the improperly recognized revenue;

(c) The Individual Defendants spoke frequently about their hands-on approach and involvement in all aspects of Catalent's business;

(d) The Individual Defendants spoke frequently about the importance of the Biologics segment and the strength of demand for its non-Vaccine products which Defendants claimed would replace falling vaccine revenues;

(e) Core Operations: Biologics was the growth area of Catalent's business going into the Class Period, and Defendants knew or recklessly disregarded that the Company could not make up for COVID-product revenues with other non-vaccine products and customers; and

(f) Defendants' admissions during and after the Class Period support an inference of scienter

A. Statements by Former Catalent Employees and Consultants Corroborate That Defendants Knew or Recklessly Disregarded the Falsity of Their Statements and Omissions at the Time the Statements Were Made.

473. The witness accounts detailed in Section IV(G) (¶¶114-266) provide factual support for the falsity of Defendants' material misstatements and omissions and for a strong

inference of scienter on Defendants' part regarding the false and misleading nature of their statements and omissions during the Class Period. The witnesses detail:

> (i) repeated GAAP violations by Catalent, including revenue recognized in violation of ASC 606 and fictitious and unsupported journal entries being directed by senior finance executives at Catalent to make the Company's financial results appear stronger than they were (¶¶215-29);
>
> (ii) material weaknesses in internal control over financial reporting, including with Catalent's inventory tracking methodology and inventory documentation (or lack thereof), and a failure to timely write off significant amounts of inventory that was unused, expired, unsaleable, or even unaccounted for (¶¶174-95, 236-41);
>
> (iii) failure to properly reserve for bad debt, including for uncollectible invoices (¶¶230-35);
>
> (iv) producing before customers wanted delivery of product and the warehousing of excess product produced before customers could take delivery (¶¶149, 205-14);
>
> (v) severe quality control issues at the Bloomington, Brussels, and Harmans/BWI facilities, which resulted in contamination and sterility issues, rampant uncorrected SOP deviations, significant remediation costs (including facility shutdowns) occasioned by the FDA's multiple Form 483s, disputes with customers for product batches that had to be thrown out, and backlogs of tens to hundreds of millions of dollars' worth of finished, but not released, products as just a few examples of the fallout from the quality issues at Catalent key production facilities (¶¶130-70, 196-204);
>
> (vi) a constant push by Catalent's senior management to keep manufacturing product despite "major quality issues" in order "to meet revenue deadlines" (¶¶146-48, 168-70, 205-14); and
>
> (vii) limited non-vaccine business in Catalent's Biologics pipeline to replace the vaccine business that was quickly drying up (¶¶245-57).

474. In addition, the witnesses cited herein detail the reporting structures, shared financial platforms, and meetings attended by Catalent's Site Leadership Team and Executive Leadership Team/Executive Committee which provided the Defendants with the information detailed above and in Section IV(G). ¶¶258-65.

B. Catalent's Improper Revenue Recognition in Q4 2022 Allowed the Company to Beat Wall Street Consensus Estimates When They Would Have Missed Consensus Estimates Without the Improperly Recognized Revenue.

475. On June 12, 2023, after the end of the Class Period, Catalent disclosed that the Company had identified an accounting error that required correction of its 2022 financial statements. Catalent had recognized revenue in violation of GAAP when it improperly accounted for a customer concession. The error resulted in a $26 million overstatement of earnings before income taxes in Q4 2022 and reduced previously reported Adjusted EBITDA by 7% and reduced Adjusted Net Income and Adjusted Net Income per Share by 12% each. ***Indeed, Catalent's restated financials show that, but for the improper revenue recognition, Catalent would have missed even the low end of Wall Street earnings guidance provided for Q4 2022***. Consequently, the error was qualitatively material to Catalent's financial statements for Q4 2022.

476. As corrected, Catalent would have missed consensus earnings targets using any of these metrics: (in $millions except per share amounts)

	Q4 2022 Adjusted EBITDA	**Q4 2022 Adjusted Net Income**	**Q4 2022 Adjusted Net Income per Share**
Consensus Estimate	$376.2	$208.2	$1.15
As Reported	$384.0 Beat	$215.0 Beat	$1.19 Beat
As Restated	$358.0 Miss	$189.0 Miss	$1.05 Miss

477. These allegations support a strong inference of scienter when considered holistically with the other strong allegations of scienter set forth herein.

C. The Individual Defendants Spoke Frequently About Their Hands-On Approach and Involvement in All Aspects of Catalent's Business

478. In their roles as CEO and CFO, Defendants Chiminski, Maselli, and Castellano were required to not only keep themselves informed of the Company's day-to-day business and operations, but also to keep Catalent's non-management directors apprised of the state of the Company's business, operations, and trends. The Individual Defendants spoke frequently about how involved they were in all aspects of the Company's business.

479. For example, the 2021 10-K (filed with the SEC on August 30, 2021) touted Defendants' hands-on involvement with setting standards and expectations for the Company, stating, in part: "Our senior management team is actively involved in setting quality policies, standards, and internal position papers as well as managing internal and external quality performance."

480. During the Q&A portion of Defendants' Q1 2022 Earnings Call (November 2, 2021), Defendant Chiminski highlighted the Company's hands-on approach:

(a) "We're constantly looking at the market. We're constantly looking at what our customers' needs are. And as a management team, working closely with our Board. We're looking out in the future to understand what strategic investments that we need to make so that we will have the capacity necessary for our customers and their pipelines."

(b) "We have engagement at the highest levels of management working with our suppliers to ensure that we get the components that we need."

(c) "And we're in constant dialogue with our Board. Every Board meeting has some component of the strategic capacity needs and CapEx that we'll need to follow on. So we're in regular dialogue here . . . ."

481. The Q1 2022 10-Q (November 2, 2021) and other quarterly reports throughout the Class Period highlighted that: "Our management, with the participation of our Chief Executive Officer and our Senior Vice President and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q."

482. The fact that the Individual Defendants spoke frequently about how involved they were in all aspects of the Company's business contributes to a finding of scienter.

D. The Individual Defendants Spoke Frequently About the Importance of the Biologics Segment and the Strength of Demand for Catalent's Non-Vaccine Products Which Defendant Claimed Would Replace Declining Vaccine Revenues.

483. As set forth above (*see, e.g.* ¶¶303-04, 324, 329-30, 343-45, 351-52, 411, 414-16) throughout the Class Period, the Individual Defendants spoke frequently about the importance of the Biologics segment and the strength of demand for Catalent's Non-Vaccine Products. For example:

(a) On the Q2 2022 Earnings Call, on February 1, 2022, Defendant Masselli said, "I'm going to continue to underline and underscore that these types of assets, specifically fill and finish lines and the regulators, are in very high demand. There is not enough capacity still in the world that would support the current volumes and the future pipeline, more importantly to prefilled syringes. And so there is demand, there is a line of customer who wanted to access[.]" ¶304.

(b) During the Q3 2022 Earnings Call, on May 3, 2022, Defendant Chiminski said, "Demand remained strong in [the Biologics] segment, including a notable increase from several of our large gene therapy customers for viral

vector manufacturing. Given the high utilization of our biologics assets as well as projections for continued demand in the years ahead, we continue to take both organic and inorganic actions to increase our footprint in drug product, drug substance and cell and gene therapy…. Viewed holistically, Catalent remains well positioned to continue delivering strong financial performance and growth." ¶322.

(c) At the Bank of America Healthcare Conference, on May 11, 2022, Defendant Castellano said, "In terms of line of sight that we have to being able to backfill COVID, a lot of this comes from the new capacity that we have that's going to be coming online across those fast growing areas that I mentioned; gene therapy, cell therapy, drug product, manufacturing the drug substance as well[.]" Castellano continued, "We're not speculatively adding capacity and then bringing it out online, having it sit idle and then keeping our fingers crossed that we're out [and] able to win new business and bring on customers to fill that . . . I would say the part of it that makes it more attractive is the fact that we're seeing a maturity of that pipeline." ¶344.

(d) On the Q4 2022 Earnings Call, on August 29, 2022, Defendant Maselli said, "[T]he transition is mostly seamless . . . So it's a kind of phase-in, phase-out type of dynamic as opposed to having a gap in between." ¶352.

(e) On the Q1 2023 Earnings Call, on November 1, 2022, Defendant Castellano stated, "I'll rank our revenue contributors biologics overall here

. . . . Our drug product business around Biologics is our largest revenue contributor here."

(f) On the 2Q 2023 earnings call, on February 7, 2023, Defendant Masselli said, "[W]hen you look at the growth in our core business, our non-COVID business, you're still seeing the business growing above market and to be honest, in the mid-teens. And when you look at Biologics specifically, even more exciting than that. So I would tell you, the market that did correct a little bit, but still supporting a very exciting growth perspective for the future. ¶416.

484. The fact that the Individual Defendants spoke frequently about the importance of the Biologics segment and the strength of demand for Catalent's Non-Vaccine products contributes to a finding of scienter.

E. Core Operations: Biologics Was the Growth Area of Catalent's Business Going into the Class Period, and Defendants Knew or Recklessly Disregarded That the Company Could Not Make Up COVID-Product Revenues with Non-Vaccine Products and Customers.

485. As discussed above, Catalent's Biologics segment was Catalent's largest and fastest-growing segment. Before the pandemic, the Biologics segment accounted for just 25% of Catalent's net revenue. By February 2022, the Biologics segment accounted for 50% of Catalent's net revenue.

486. Throughout the Class Period, Defendants' frequently spoke about the importance of the Biologics segment to Catalent's future growth and margin expansion. A few examples are highlighted below.

487. On January 10, 2022, at the J.P. Morgan 2022 Healthcare Conference, Defendant Chiminski boasted:

> The Biologics segment, which includes our drug product, drug substance and cell and gene therapy offerings, has become our largest business segment. It's also our fastest-growing segment and is expected to be the primary driver of margin expansion for the company over time as the investments we've made to scale the business continue to come online and their overall capacity utilization grows.

488. On January 9, 2023, at the J.P. Morgan 2023 Healthcare Conference, Defendant Maselli stated:

> The role of biologics is really to be a growth accelerator and a margin enhancer for the organization. At the same time, it's also attracting most of the capital deployment that we have into the organization. So here, we have built a comprehensive set of capabilities, end-to-end from drug substance to drug product, bioanalytical services, cell and gene therapies, becoming a powerhouse of the biopharma ecosystem.

489. Analysts covering Catalent also frequently wrote about the importance of the Biologics segment to the Company's growth rate. For example, an August 29, 2022 report, Barclays' analysts noted: "investors are not buying CTLT for the small molecule and consumer health businesses, which is why they focus all of their energy/time on biologics and [Cell Therapy/Gene Therapy]."

490. Given the core nature of Biologics to Catalent's business and operations, there is a strong inference that Defendants knew or recklessly disregarded the negative impact that a slowdown in revenues and growth in the Biologics segment would have on Catalent's revenues and growth.

F. Defendants' Admissions During and After the Class Period Support an Inference of Scienter

491. Defendants made a number of admissions both during and after the Class Period that support an inference of scienter. First, on November 16, 2022, then CFO-Castellano revealed that Catalent was carrying approximately $400 million in excess inventory. While the

Company increased its inventory reserves for fiscal Q1 2023 (ended September 30, 2022), the increase was less than 10% of the increase Catalent's CFO concluded was necessary at the time. The modest increase also failed to account for excess levels of inventory with exposure to expiration, decreasing customer demand, and the fact that Catalent routinely was providing price concessions to customers as an inducement to avoid incurring inventory write-downs.

492. Second, on April 14, 2023, Catalent revealed productivity issues, remediation costs, and other "operational challenges" at its key production facilities at Bloomington, Brussels, and Harmans/BWI. The Company simultaneously disclosed that it had parted ways with Defendant Castellano "with immediate effect."

493. Third, on June 12, 2023, Catalent filed restated financial statements for fiscal 2022 ended June 30, 2022 because of the improper recognition of revenue associated with price concession given to a customer (the inclusion of which allowed Catalent to meet Wall Street earnings guidance provided for Q4 2022). Catalent also reported a material weakness in internal controls over financial reporting as of June 30, 2022 and recorded a $55 million charge in Q3 2023 to increase the Company's inventory reserves to account for unsaleable inventory. The Company also admitted that it failed to apply "rigor and skepticism" in its business processes.

494. Then, on August 30, 2023, Catalent revealed that the filing of its Form 10-K for fiscal year 2023 ended June 30, 2023 would be delayed as the Company "requires additional time to complete its procedures related to management's assessment of the effectiveness of its internal controls over financial reporting as of June 30, 2023 and other closing procedures." Two weeks later, on September 15, 2023, Catalent announced it had received notice from the NYSE that it was "not in compliance with the NYSE's continued listing requirements" as the Company had failed to file the 10-K by the extension date of September 13, 2023.

495. These admissions by the Company, over the course of several months beginning in the middle of the Class Period and continuing after its end, support an inference of scienter.

VIII. LOSS CAUSATION/ECONOMIC LOSS

496. Defendants' misstatements and omissions, as alleged herein, directly and proximately caused the economic loss suffered by Lead Plaintiffs and the Class. Throughout the Class Period, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to defraud investors. Defendants' misstatements and omissions artificially inflated and/or artificially maintained the price of Catalent securities and operated as a fraud and deceit on the Class. During the Class Period, Lead Plaintiffs and the Class purchased Catalent securities at artificially inflated and/or artificially maintained prices, and were damaged thereby when the price of Catalent's securities declined when the truth was revealed and/or the risks concealed by Defendants' misrepresentations and omissions materialized.

497. Specifically, Defendants made false and misleading statements and omissions about: (1) the Company's compliance with GAAP in its revenue recognition practices; (2) the appropriateness, under GAAP, of the level of the Company's inventory reserves for unsaleable inventory related to the manufacture of COVID vaccines; (3) Catalent's internal controls over financial reporting related to revenue recognition and forecasting; (4) the Company's compliance with CGMP, quality control, and safety regulations that are enforced by the FDA; (5) the ongoing "operational challenges" that plagued three of the Company's most important manufacturing facilities and "the significant disruption from remediation efforts" at those facilities; (6) demand for the Company's gene therapy and other non-vaccine products in the Biologics and Pharma and Consumer Health segments which the Company represented would more than offset COVID revenue declines during the Class Period; and (7) how quickly and easily Catalent would be able to transition its production lines and personnel from COVID

vaccine production to the production of other products at its largest facilities including the Bloomington, Indiana facility. When Defendants' prior misrepresentations and fraudulent conduct were disclosed to investors, the price of Catalent's securities dropped significantly.

498. As a result of the disclosure of the truth of Defendants' fraud and/or materialization of the risks through the series of disclosures described below, investors incurred hundreds of millions of dollars in losses.

499. As described below, Catalent's misrepresentations and omissions were revealed to the market through a series of six (6) partial disclosures from September 20, 2022, through May 8, 2023.

A. September 20, 2022: Washington Post Article (First Partial Disclosure)

500. The truth behind Catalent's misrepresentations and omissions about the Company's failure to comply with CGMP began to come to light on September 20, 2022, when the *Washington Post* released an article, after the close of trading, entitled "FDA releasing millions of Moderna boosters as states warn of shortages." According to the article, the FDA had delayed the release of millions of COVID-19 vaccine booster shots filled by Catalent because of the poor inspection and resulting Form 483 issued to Catalent at its Bloomington facility. FDA officials raised concerns that vaccines packaged at the Bloomington facility could be contaminated because the facility was not sufficiently sterile. On this news, Catalent's stock price ***declined by 9.3 percent*** over two trading sessions, falling from $87.15 per share on September 20, 2022, to close at $79.06 per share on September 22, 2022.

B. November 1, 2022: Q1 2023 Financial Results (Second Partial Disclosure)

501. On November 1, 2022, in connection with the release of disappointing Q1 2023 financial results, Catalent disclosed that its quarterly earnings had **declined to zero**, and lowered its fiscal year 2023 revenue guidance due to, among other things, lowered spending by some of

its customers. The earnings miss and revised guidance revealed that demand for Catalent products was much weaker than the Company had been touting. On this news, Catalent's stock price ***plunged by 31.7 percent*** over two trading sessions, to close at $44.90 per share on November 2, 2022.

C. November 16, 2022: Stephens Investment Conference (Third Partial Disclosure)

502. Defendants' gradual revelation of the truth continued on November 16, 2022, when Catalent revealed that it was carrying approximately $400 million in excess inventory, further revealing that the Company had misrepresented demand for its products as well as its purported ability to predict future demand. On this news, Catalent's stock price ***declined by 14 percent*** over two trading sessions, to close at $42.07 per share on November 17, 2022.

D. December 8, 2022: GlassHouse, LLC Issues Damning Research Report on Catalent's Accounting Practices (Fourth Partial Disclosure)

503. Defendants' fraud was also partially revealed on December 8, 2022, when GlassHouse Research published a report claiming that Catalent had been prematurely recognizing revenues of at least $568.2 million in violation of GAAP. The report detailed numerous red flags that were indicative of Catalent's improper accounting practices. These red flags included: (i) the rapid increase in Catalent's contract asset and inventory balances; (ii) declining customer deposits; (iii) executive turnover; and (iv) scrutiny of the Company's revenue accounting by regulators. The report also described how Catalent's direct customers were stuffed with excess inventory which "will take years to unwind." On the news of the GlassHouse Research report, Catalent's stock price ***declined 3.6 percent*** to close at $45.54 per share on December 8, 2022.

E. April 14, 2023: Business Update (Fifth Partial Disclosure)

504. Defendants' gradual revelation of the truth continued on April 14, 2023, when Catalent revealed it expected productivity issues and higher-than-expected costs at three of its largest manufacturing facilities -- Bloomington, Brussels, and Harmans/BWI -- to materially and adversely impact the Company's financial results for Q3 2023 (ended March 31, 2023), and its outlook for the remainder of fiscal year 2023 (ended June 30, 2023). The Company explained it was unable to achieve anticipated productivity levels and associated revenue due to costs related to remediation at several of its facilities following regulatory inspections that resulting in FDA Reports on Form 483 and other "operational challenges" the Company was facing. On this news, Catalent's stock price ***declined 26.8 percent*** to close at $46.32 per share on April 14, 2023.

F. May 8, 2023: Announcement of Accounting Adjustments and More (Sixth Disclosure)

505. On May 8, 2023, Catalent shocked the market by disclosing that it would be delaying the release of its third fiscal quarter results and would be filing a Form 12b-25, Notification of Late Filing, with the SEC because, in addition to the productivity and cost issues identified on April 14, 2023, the Company also: (i) identified accounting issues related to its operations at the Bloomington, Indiana manufacturing facility; (ii) expected to record a goodwill write-down in its consumer health segment; and (iii) significantly reduced its forecasts for fiscal year 2023 (ended June 30, 2023). On this news, Catalent's stock price ***declined 25.7 percent*** to close at $35.46 per share on May 8, 2023.

506. It was entirely foreseeable to Defendants that their materially false and misleading statements and omissions would artificially inflate and artificially maintain the price of Catalent's securities. It was also foreseeable to Defendants that the revelation of the truth about the issues described herein, or the materializations of the risks concealed by Defendants, would

cause the price of the Company's securities to fall as the artificial inflation caused by Defendants' misstatements and omissions was removed. Lead Plaintiffs and other Class members suffered actual economic losses and were damaged when the foreseeable risks, including, but not limited to, the risks of adverse facility inspections by regulators, delay of filing or restatement of the Company's financial statements, earnings misses, and other adverse impacts on financial performance, materialized through the gradual disclosure of new information concerning the alleged fraud. Thus, the stock price declines described above were directly and proximately caused by Defendants' materially false and misleading statements.

IX. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

507. To the extent that the Defendants concealed or improperly failed to disclose material facts with regard to the Company, Lead Plaintiffs are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

508. Further, Lead Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) Defendants' omissions and misrepresentations were material;

(c) the Company's securities traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) Lead Plaintiffs and other members of the Class purchased Catalent securities between the time Defendants misrepresented or failed to

disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

509. At all relevant times, the market for Catalent securities was efficient for the following reasons, among others:

(a) as a regulated issuer, Catalent filed periodic public reports with the SEC;

(b) Catalent regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services;

(c) Catalent was followed by several securities analysts employed by major brokerage firm(s) who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firm(s) and that were publicly available and entered the public marketplace; and

(d) Catalent securities were actively traded on the NYSE.

510. As a result of the foregoing, the market for Catalent securities promptly digested current information regarding Catalent from all publicly available sources and reflected such information in Catalent's stock price. Under these circumstances, all purchasers of Catalent securities during the Class Period suffered similar injury through their purchase at artificially inflated prices and the presumption of reliance applies.

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

511. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded in this

Complaint. The statements complained of herein were historical statements or statements of current facts and conditions at the time the statements were made. Further, to the extent that any of the false or misleading statements alleged herein could be construed as forward-looking, the statements were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements.

512. Alternatively, to the extent the statutory safe harbor otherwise would apply to any forward-looking statements pleaded herein, Defendants are liable for those false and misleading forward-looking statements because at the time each of those statements was made, the speakers knew the statement was false or misleading, or the statement was authorized or approved by an executive officer of Catalent who knew that the statement was materially false or misleading when made.

513. Additionally, the risk disclosures included in Catalent's public filings were inadequate, obfuscated the truth, and did not inform investors of the true facts and actual risks already occurring.

XI. CLASS ACTION ALLEGATIONS

514. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23 on behalf of a Class consisting of all persons and entities who or which purchased or otherwise acquired the publicly traded common stock or exchange-traded call options or sold exchange-traded put options of Catalent during the Class Period (the "Class"), and were damaged thereby. Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer, director, and/or control person of Catalent during the Class Period; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling interest; (v) Catalent's employee retirement and benefit plan(s) and their participants or beneficiaries, to the extent they made

purchases through such plan(s); and (vi) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person or entity, in their capacities as such.

515. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Catalent's common stock was actively traded on the NYSE. As of March 30, 2023, there were more than 180 million shares of Catalent common stock outstanding. Although the exact number of Class members is unknown to Lead Plaintiffs at this time, Lead Plaintiffs believe that there are at least thousands of members of the proposed Class. Members of the Class can be identified from records maintained by Catalent or its transfer agent(s) and may be notified of the pendency of this action by publication using a form of notice similar to that customarily used in securities class actions.

516. Lead Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

517. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Lead Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

518. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act was violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of the Company;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

- whether the Defendants caused the Company to issue false and misleading filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false filings;
- whether the prices of Catalent securities during the Class Period were artificially inflated or artificially maintained because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

519. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

For Violations of Section 10(b) of the Exchange Act And Rule 10b-5 Promulgated Thereunder Against All Defendants

520. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

521. This Count is asserted against Defendants based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

522. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

523. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Catalent securities during the Class Period.

524. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated in or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

525. Individual Defendants, who are or were senior executives and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Lead Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Catalent personnel to members of the investing public, including Lead Plaintiffs and the Class.

526. As a result of the foregoing, the market price of Catalent securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Lead

Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of Catalent securities during the Class Period in purchasing Catalent securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

527. Had Lead Plaintiffs and the other members of the Class been aware that the market price of Catalent securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased Company securities at the artificially inflated prices that they did, or at all.

528. As a result of the wrongful conduct alleged herein, Lead Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

529. By reason of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and are liable to the Lead Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchase of Catalent securities during the Class Period.

COUNT II

For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

530. Lead Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

531. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, the Individual

Defendants knew the adverse non-public information about the Company's misstatement of revenue and profit and false financial statements.

532. As officers of a public business, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to promptly correct any public statements issued by the Company which had become materially false or misleading.

533. Because of their positions of control and authority as senior executives and/or directors, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Catalent securities.

534. By reason of the above conduct, the Individual Defendants are jointly and severally liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs, on behalf of themselves and the Class, pray for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating SEB Investment Management AB and Public Employees' Retirement System of Mississippi as Lead Plaintiffs and certifying Lead Plaintiffs as Class Representatives under Rule 23 of the Federal

Rules of Civil Procedure and designating Lead Plaintiffs' counsel, Labaton Sucharow LLP as Class Counsel;

(b) awarding damages in favor of Lead Plaintiffs and the other Class members against all Defendants, jointly and severally, together with interest thereon;

(c) awarding Lead Plaintiffs and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding Lead Plaintiffs and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Lead Plaintiffs hereby demand a trial by jury.

Dated: September 15, 2023

Respectfully submitted,

/s/ James E. Cecchi

CARELLA, BYRNE, CECCHI, BRODY & AGNELLO, P.C.
James E. Cecchi
5 Becker Farm Road
Roseland, NJ 07068
Telephone: (973) 994-1700
jcecchi@carellabyrne.com

Liaison Counsel for the Class

LABATON SUCHAROW LLP
Christine M. Fox (*pro hac vice*)
Joseph Cotilletta (047092011)
James M. Fee (*pro hac vice*)
140 Broadway
New York, NY 10005
Telephone: (212) 907-0700
cfox@labaton.com
jcotilletta@labaton.com
jfee@labaton.com

KESSLER TOPAZ MELTZER & CHECK, LLP
Andrew L. Zivitz (*pro hac vice*)
Matthew L. Mustokoff (*pro vice hac pending)*
Jamie M. McCall *(pro vice hac pending)*
Margaret E. Mazzeo (*pro hac vice*)
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
azivitz@ktmc.com
mmustokoff@ktmc.com
jmccall@ktmc.com
mmazzeo@ktmc.com

Co-Lead Counsel for Lead Plaintiffs SEB Investment Management AB and Public Employees' Retirement System of Mississippi, and the Proposed Class